

Investigational Drug Branch Drug Development Plan Tool version 2.1 User Training Document



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IDB Drug Development Plan Tool Purpose

- Use MS Project to visually represent the temporal data stored in CTEP's enterprise database
- Allow IDB drug monitors and TRI clinical research experts to easily display, review, and share information about clinical trial milestones and accruals

IDB Drug Development Plan Tool Training Goals

Teach individual users how to:

- Find, start, and log on to the tool
- Select clinical trial protocols and letters of intent with the tool
- Chart clinical trial milestones with the tool
- Read Gantt chart symbols and notes
- Add notes and user-defined tasks to a Gantt chart
- Print and save a Gantt chart
- Report problems and ask questions about the tool

Training Scenario Overview

A Clinical Research Specialist (CRS) with TRI receives a clinical trial Quarterly Report from a principal investigator. The CRS uses the IDB Drug Development Plan Tool to accomplish the following:

- Review amendment dates for the clinical trial
- Communicate information about responses and phase II solicitations to the IDB Monitor
- Print and save charts for later discussion of the the trial's progress

Training Information Conventions

Three types of information are presented in the training scenario. Each type of information appears in a different type of box.

Scenario Element:

Information about what is happening in the scenario appears in this type of box with this type of text.

Tool Use

Information about how to use the tool features appears in this type of box with this type of text.

Technical Info

Information about the technology behind the tool appears in this type of box with this type of text.

Scenario Elements

NOTE: All scenario elements are hypothetical!

Scenario Element:

A Principal Investigator submits a Quarterly Report for the Phase I trial T97-0118.

Scenario Element:

A CRS at TRI reviews the Quarterly Report and notes the following information:

- Two patients are showing response to the agent
- The study is reaching Maximum Tolerated Dose

Scenario Element:

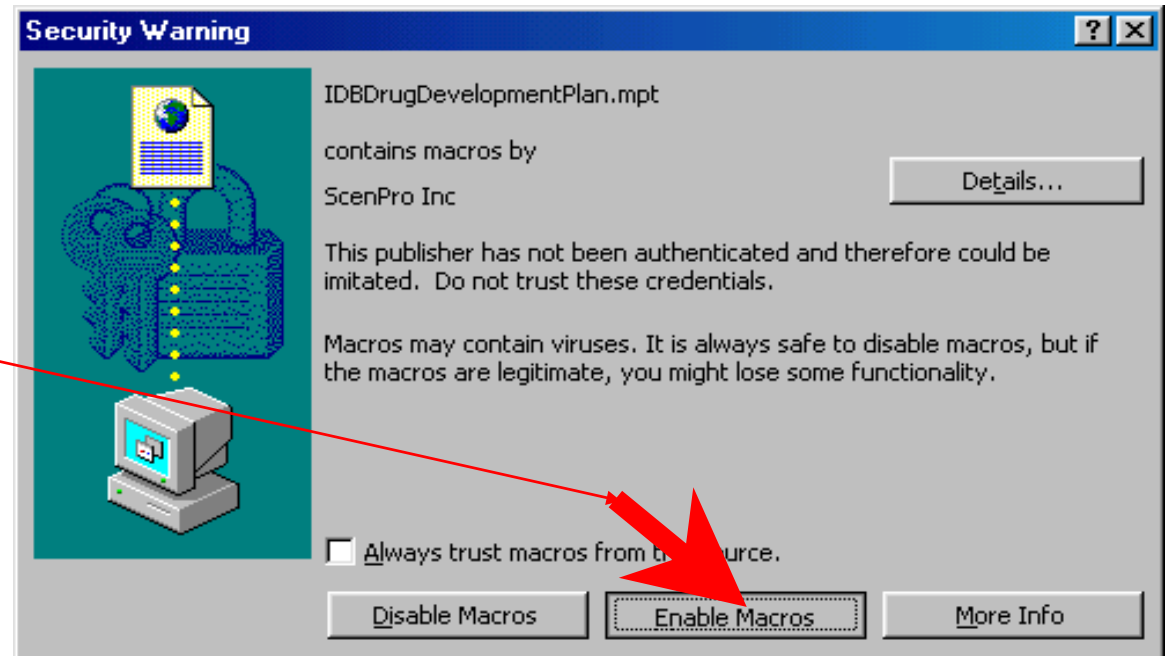
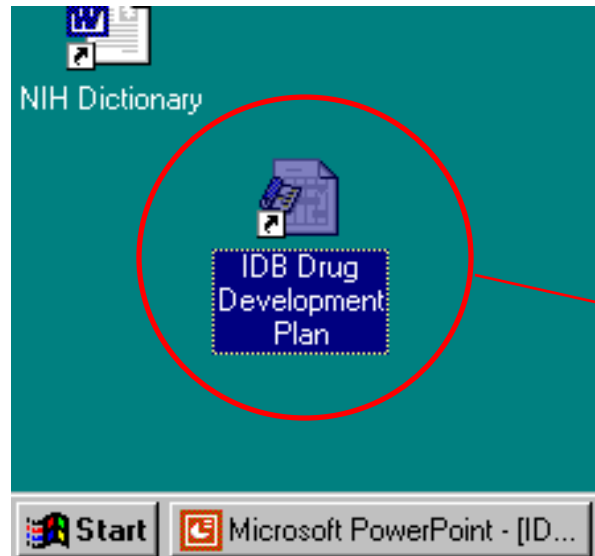
The CRS decides that some of this information should be communicated to the IDB Drug Monitor for the study.

Investigational Drug Branch Drug Development Plan Tool



Selecting and Charting a Study

Starting the Tool via the Desktop Shortcut



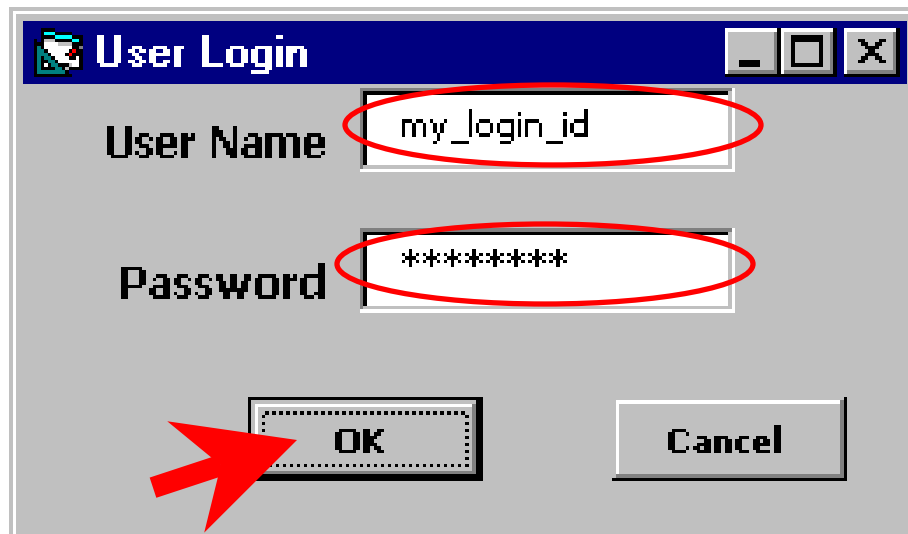
Scenario Element:

The CRS opens the IDB Drug Development Plan Tool by double-clicking on the desktop icon and by enabling macros if prompted .

Logging on to the Database

Scenario Element:

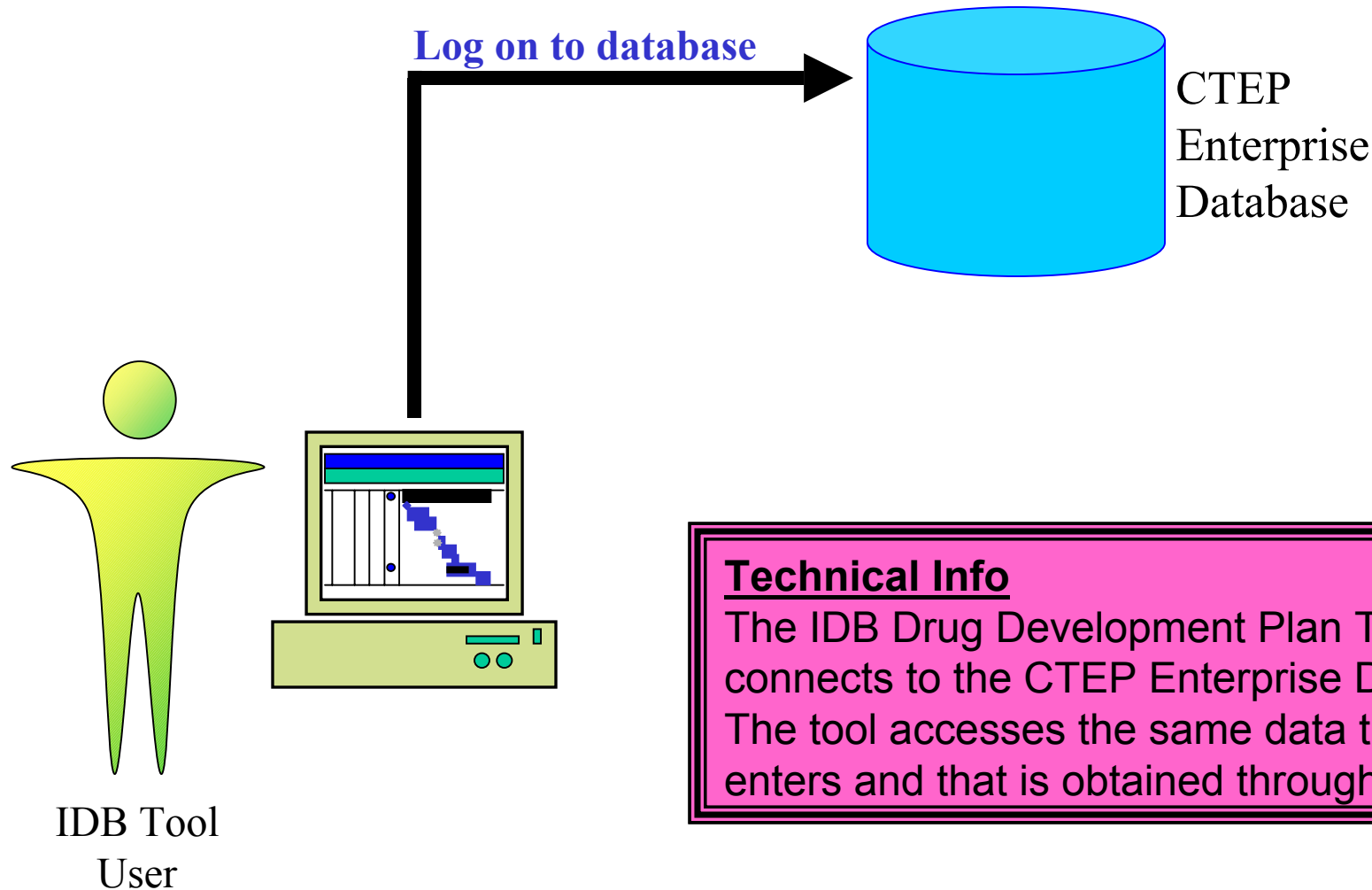
The CRS logs into the IDB Drug Development Plan using her/his own id and password. This is the same ID and password used to access any CTEP-ESYS application.



Tool Use

Once the MS Project file opens, the User Login dialog box will appear. You may type in your **User Name** and **Password** to access the database. Then click **OK** or press the Enter key. Please note that if you click **Cancel**, you will not be able to use the IDB Drug Development Plan until you exit MS Project and then restart the application.

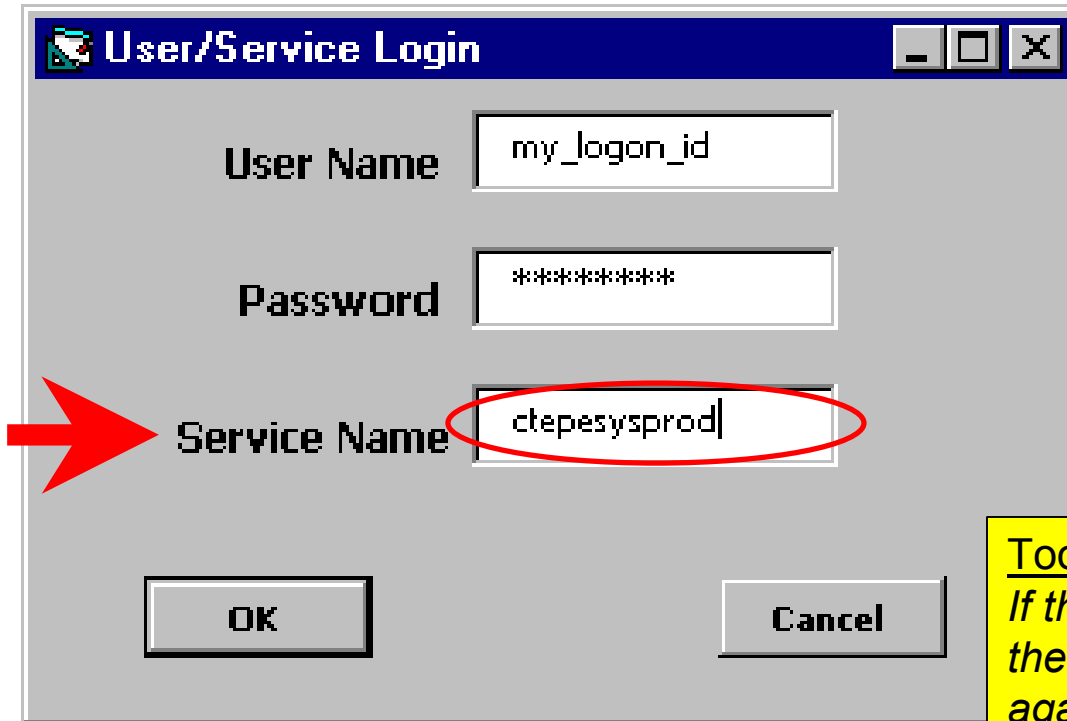
Logging on to the Database



Technical Info

The IDB Drug Development Plan Tool connects to the CTEP Enterprise Database. The tool accesses the same data that PIO enters and that is obtained through CDUS.

Logging on to the Database



The image shows a 'User/Service Login' dialog box with a blue title bar. It contains three input fields: 'User Name' with the text 'my_logon_id', 'Password' with masked characters '*****', and 'Service Name' with the text 'ctepesysprod'. A red arrow points to the 'Service Name' field, which is also circled in red. At the bottom are 'OK' and 'Cancel' buttons.

User Name	my_logon_id
Password	*****
Service Name	ctepesysprod

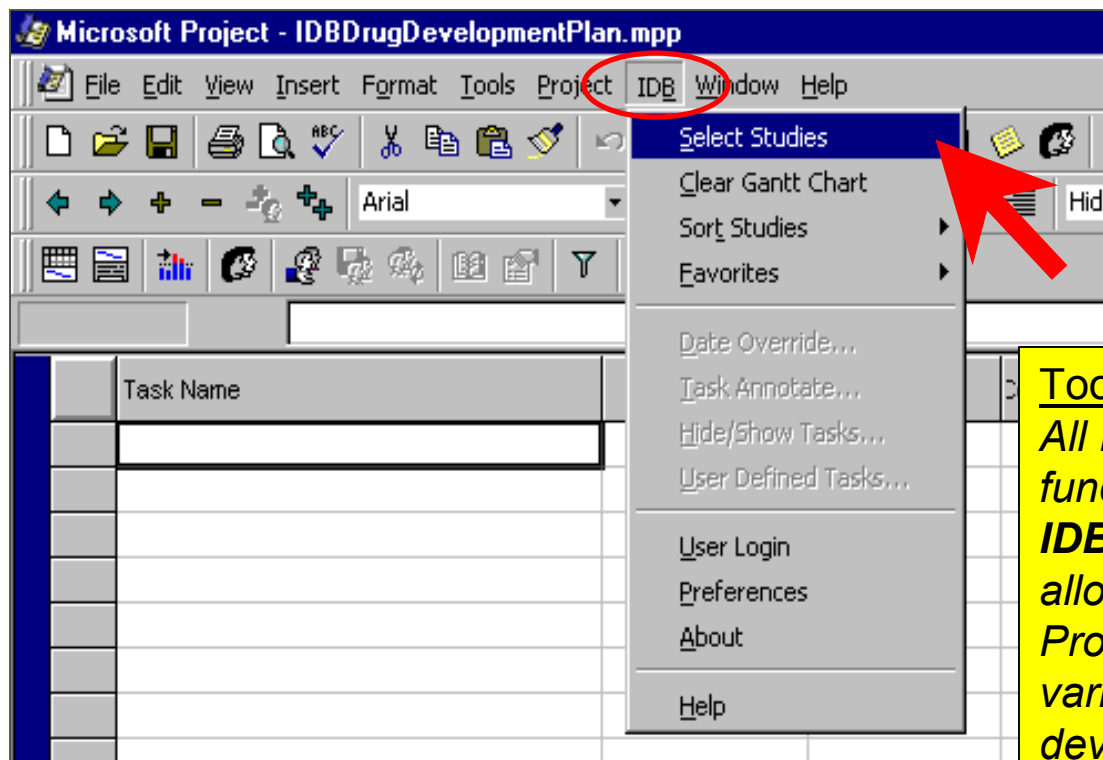
Tool Use

*If the user makes a mistake logging on to the database, she or he will be asked to try again at the User/Service Login dialog box. For this type of login, the user must enter the Service Name along with the ID and password. The Service Name for the CTEP-ESYS database is **ctepesysprod**. That stands for CTEP-ESYS Production.*

Starting a Search for a Study

Scenario Element:

The CRS decides to use the IDB Tool to find study T97-0118. The CRS uses the *Select Studies* command on the IDB menu.



Tool Use

All IDB Drug Development Plan functions may be accessed from the **IDB** Menu. The *Select Studies* option allows the user to search for clinical trial Protocols and Letters of Intent by a variety of means to use in the development of Gantt Charts

Starting a Search for a Study

Select Studies

by IDB Monitor | by Agent | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents: Find Studies

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☒ LOI ☒ Protocol

Clear Selections

Select All

Query is processing, please wait....

OK Cancel

Tool Use

When the **Select Studies** command is used, the *Select Studies* dialog box opens. There may be a brief delay while information is queried from the database. During this delay, the message "Query is processing, please wait..." will appear in the message area near the bottom of the dialog box.

Searching for a Study by Agent

Scenario Element:

Since the CRS decides to search for the study in question by using its Agent, Cisplatin.

The screenshot shows the 'Select Studies' window with the following elements:

- Tabbed interface: 'by IDB Monitor', **by Agent** (selected and circled), 'by Principal Investigator', 'by Institution', 'by Disease', 'by Keyword', 'by IND No.'
- Search input: A text box containing 'D, L, - amygdalin' (NSC#251222) with a dropdown arrow.
- Buttons: 'Find Studies', 'Clear Selections', 'Select All'.
- Filters: 'Studies to Search' section with checkboxes for 'In Review', 'Active' (checked), 'Closed', 'OWN', 'LOI' (checked), and 'Protocol' (checked).
- Message: 'Please select an item from combo box'.

Tool Use
*In order to search for studies by Agent, the user clicks on the tab that says **by Agent**.*

Searching for a Study by Agent

Select Studies

by IDB Monitor | **by Agent** | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents: "D, L, - amygdalin" (NSC#251222) Find Studies

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☒ LOI ☒ Protocol

Clear Selections

Select All

Please select an item from combo box

OK Cancel

Tool Use

The user may choose an agent from a list of All Agents in the CTEP database, or from a list of only Agents for which CTEP owns the IND. The user makes this selection by clicking on the appropriate radio button.

Searching for a Study by Agent

Select Studies

by IDB Monitor **by Agent** by Principal Investigator by Institution by Disease by Keyword by IND No.

Agents: "D, L, - amygdalin" (NSC#251222)

Studies to Search:
☐ In Review ☒ Active

Please select an item from combo box

Find Studies

Clear Selections

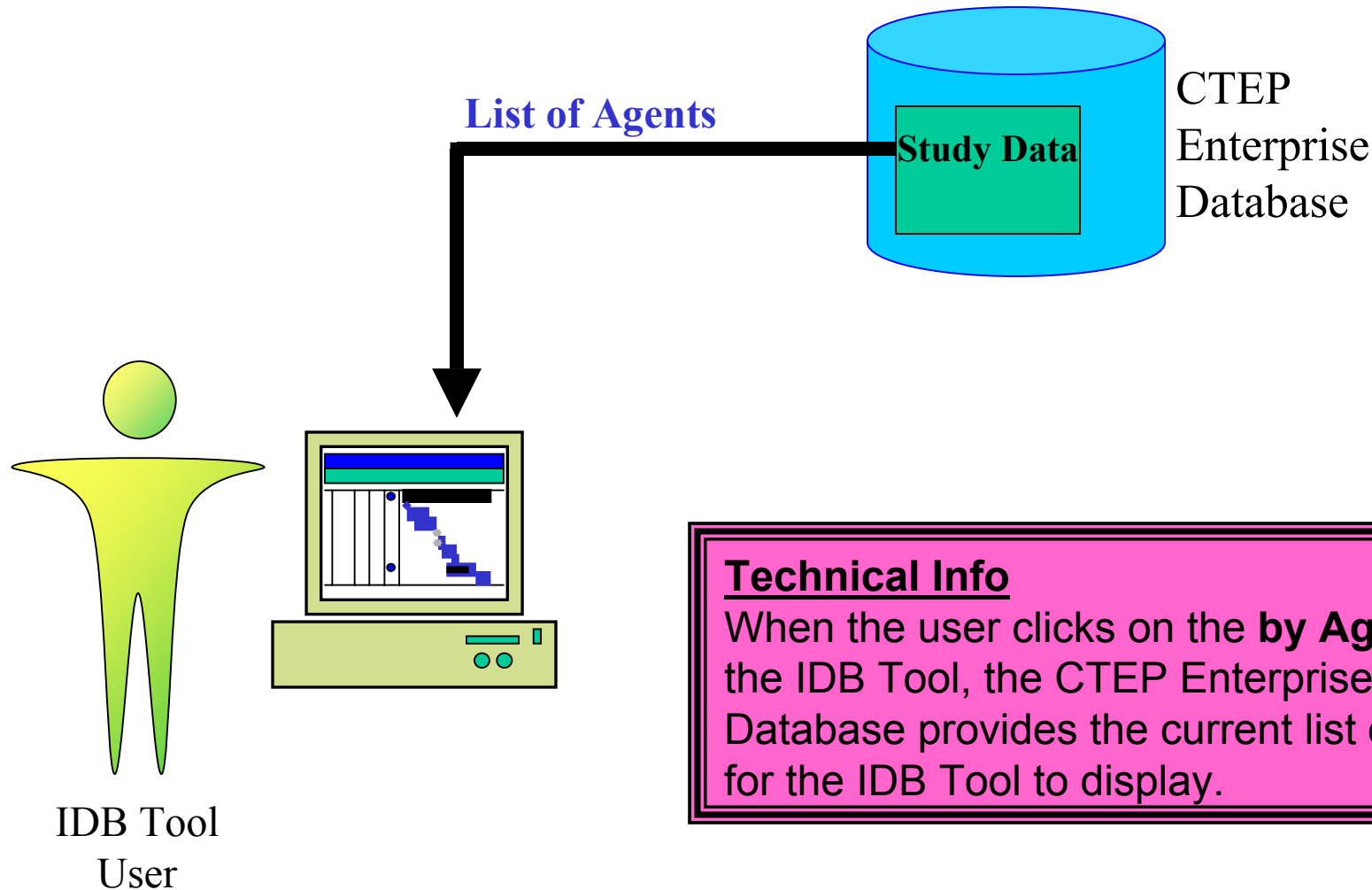
Select All

OK Cancel

Tool Use

The drop-down list shows all the Agents that the user may select from in order to find a study. The user may move through the list using the mouse, or may use the page up, page down and arrow keys.

Searching for a Study by Agent



Technical Info

When the user clicks on the **by Agent** tab in the IDB Tool, the CTEP Enterprise Database provides the current list of Agents for the IDB Tool to display.

Searching for a Study by Agent

Select Studies

by IDB Monitor | **by Agent** | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents: **CISPLATIN (NSC#119875)**

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☒ LOI ☒ Protocol

Find Studies

Clear Selections

Select All

OK Cancel

Tool Use

*Rather than scrolling, the user may type the the first letter of the Agent name into the **Agents** field. The first Agent beginning with that letter will automatically be highlighted. The user may then scroll from that point to find the Agent he or she wants.*

Searching for a Study by Agent

Scenario Element:

The CRS has set the search criteria to find all Active Protocols for Cisplatin.

Select Studies

by IDB Monitor by Agent by Principal Investigator by Institution by Disease by Keyword by IND No.

Agents CISPLATIN (NSC#119875) Find Studies

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☐ LOI ☒ Protocol

Clear Selections

Select All

hit 'Find Studies' button to get study list

OK Cancel

Tool Use

The user may apply filters to the search for studies. The user may specify any combination of study statuses (Active, Closed, etc.) and document types (LOI or Protocol).

Searching for a Study by Agent

Scenario Element:

The CRS clicks the Find Studies button to find all the Active Protocols for Cisplatin.

Select Studies

by IDB Monitor | **by Agent** | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents: **Find Studies**

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☐ LOI ☒ Protocol

Clear Selections
Select All

Please hit 'Find Studies' button to get study list

OK **Cancel**

Tool Use

Click the Find Studies button to retrieve the complete list of studies using this Agent.

Searching for a Study by Agent

Select Studies

by IDB Monitor | **by Agent** | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents:

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☐ LOI ☒ Protocol

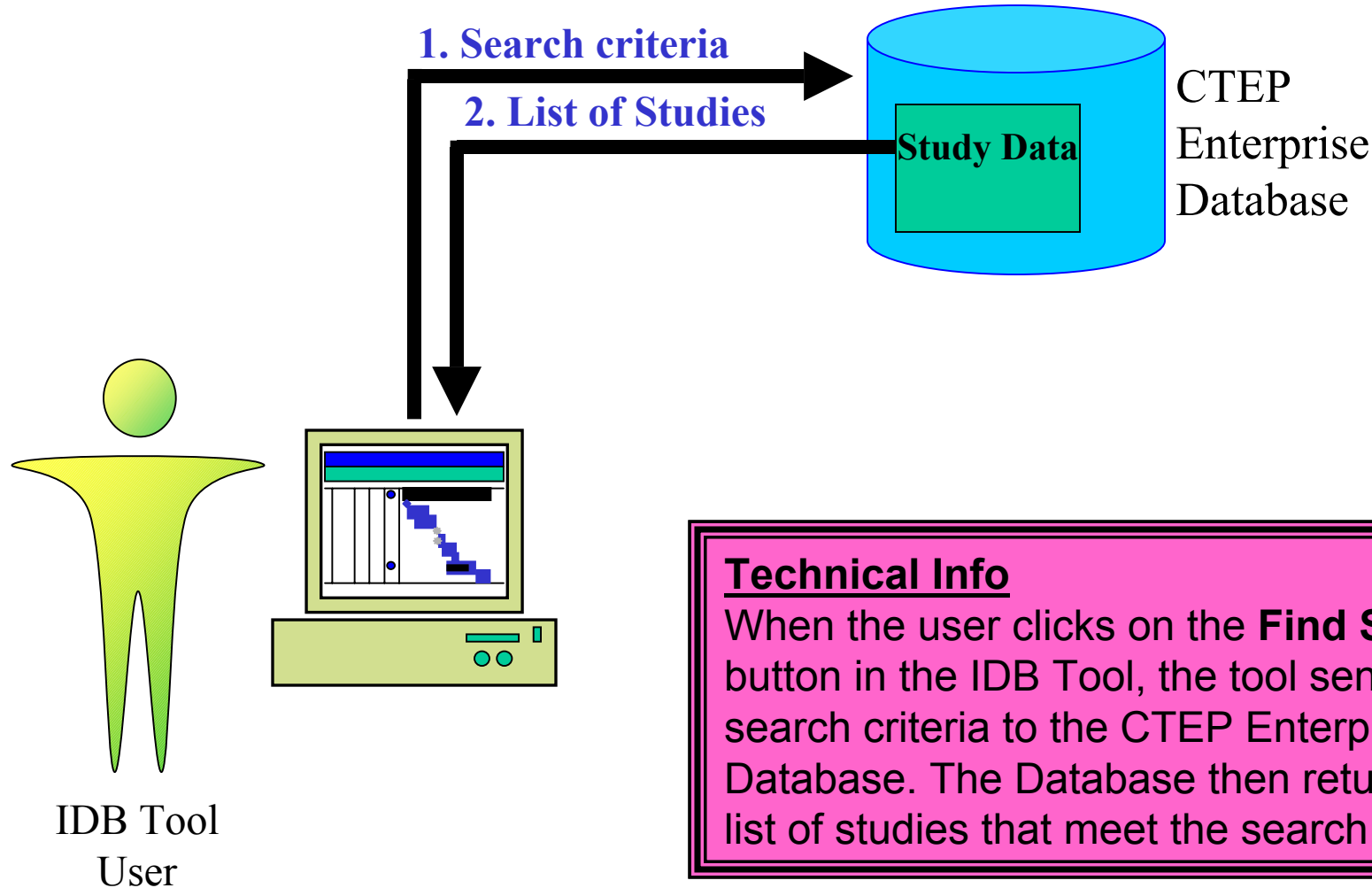
DOC. NO.	TITLE	PHASE
59623	A comparison of intensive sequential chemotherapy using doxorubi...	III
CCG-99701	A group-wide pilot study of concurrent carboplatin, vincristine and r...	I/II
GOG-0076Z	A limited access Phase II trial of Cisplatin and Navelbine (Vinorelb...	II
GOG-9805	A limited access trial using Amifostine for protection against Cisplati...	II
TOX-9900	A Phase I and PHARMACOKINETIC study of Cisplatin...	

To select more than one study, hold down the Ctrl key while clicking. **Records: 73**

Tool Use

A list of all currently active studies using the Agent Cisplatin appears in the Document Window. The number of studies found appears below the Document Window.

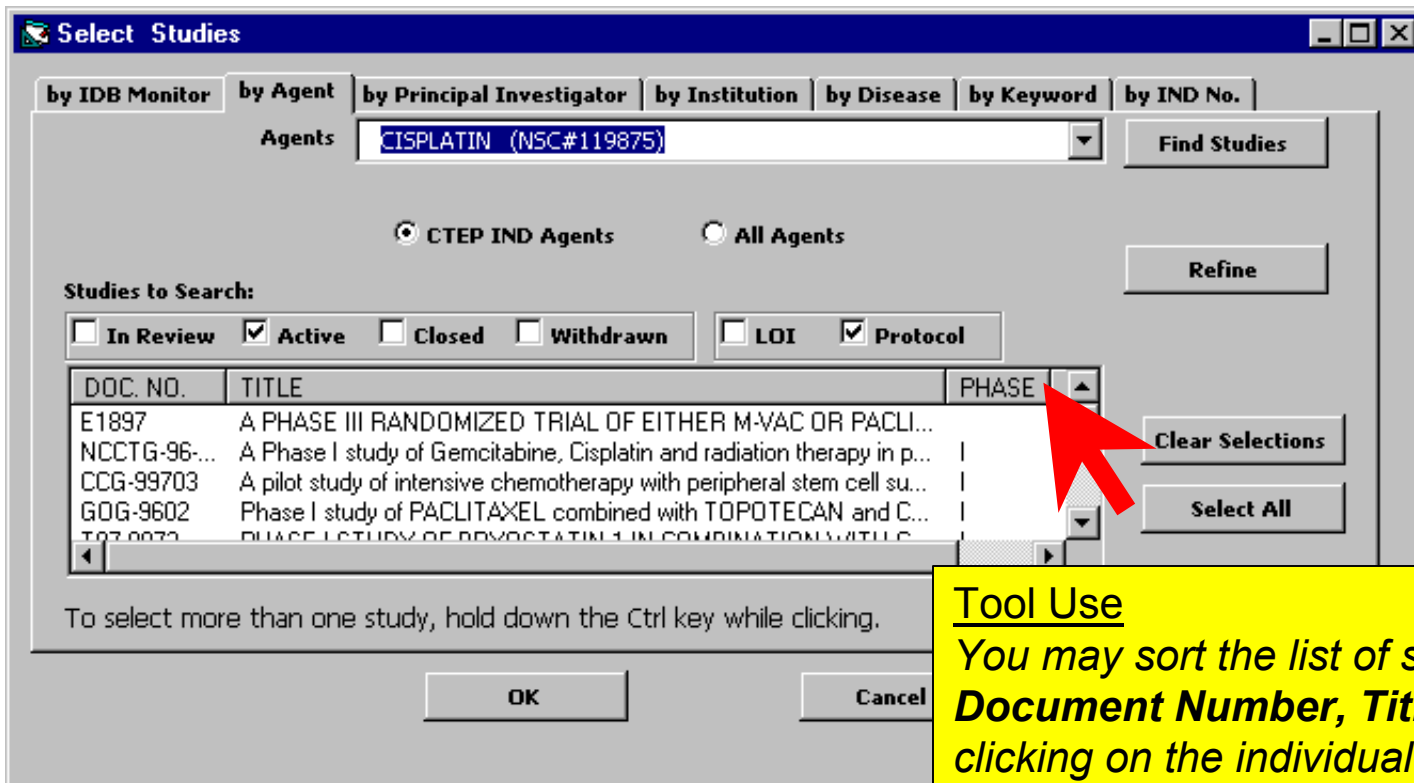
Searching for a Study by Agent



Sorting the List of Studies

Scenario Element:

The CRS knows that T97-0118 is a phase I study, so she clicks on the “Phase” heading to sort the study list by phase.



Select Studies

by IDB Monitor | by Agent | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents:

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☐ LOI ☒ Protocol

DOC. NO.	TITLE	PHASE
E1897	A PHASE III RANDOMIZED TRIAL OF EITHER M-VAC OR PACLI...	
NCCTG-96-...	A Phase I study of Gemcitabine, Cisplatin and radiation therapy in p...	
CCG-99703	A pilot study of intensive chemotherapy with peripheral stem cell su...	
GOG-9602	Phase I study of PACLITAXEL combined with TOPOTECAN and C...	
T97-0072	PHASE I STUDY OF DDVACITABINE IN COMBINATION WITH C...	

To select more than one study, hold down the Ctrl key while clicking.

Tool Use

You may sort the list of studies by **Document Number**, **Title**, or **Phase** by clicking on the individual column heading. The list will sort immediately.

Selecting a Study to Chart

Scenario Element:

The CRS finds study T97-0118 in the list among the phase I studies. She clicks on T97-0118 to highlight it.

Select Studies

by IDB Monitor | **by Agent** | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents:

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☐ LOI ☒ Protocol

DOC. NO.	TITLE	PHASE
T97-0058	Phase I Study Of Bryostatin-1 (Nsc 339555) And Cisplatin In Advan...	I
T97-0118	An Open-Label, Non-Randomized Phase I Study Of The Protein Ki...	I
T98-0069	Phase I And PHARMACOKINETIC Study Of Sequences Of NS...	I
RT0G-97-12	Phase I/II dose escalation study of thoracic irradiation with conc...	I/II
CCC-00701	Phase I/II dose escalation study of thoracic irradiation with conc...	I/II

To select more than one study, hold down the Ctrl key on the keyboard while clicking on studies.

Tool Use

Click on studies in the Document Window to select them as subjects for Gantt charts. To select more than one study, hold down the Ctrl key on the keyboard while clicking on studies.

Creating a Gantt Chart

Scenario Element:

The CRS creates a Gantt Chart of the study by clicking the OK button.

Select Studies

by IDB Monitor | by Agent | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Agents:

☒ CTEP IND Agents ☐ All Agents

Studies to Search:

☐ In Review ☒ Active ☐ Closed ☐ Withdrawn ☐ LOI ☒ Protocol

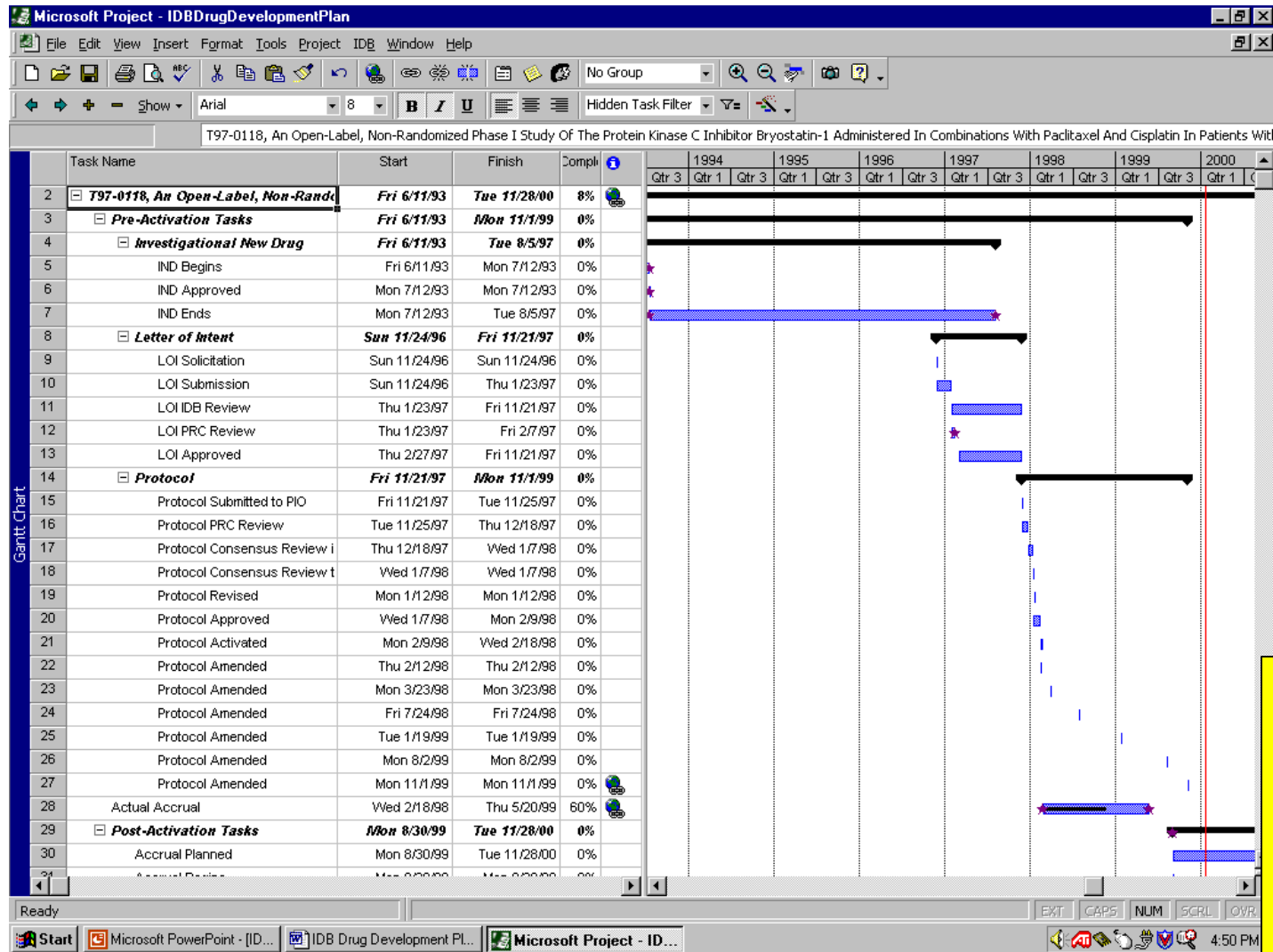
DOC. NO.	TITLE	PHASE
CCG-99703	A pilot study of intensive chemotherapy with peripheral stem cell su...	I
T97-0118	An Open-Label, Non-Randomized Phase I Study Of The Protein Ki...	I
T96-0091	An Open-Label, Non-Randomized Phase I Study Of The Protein Ki...	I
T97-0058	Phase I Study Of Bryostatin-1 (Nsc 339555) And Cisplatin In Advan...	I
T97-0072	PHASE I STUDY OF BRYOSTATIN-1 IN COMBINATION WITH C...	I

To select more than one study, hold down the Ctrl key while clicking. Records:

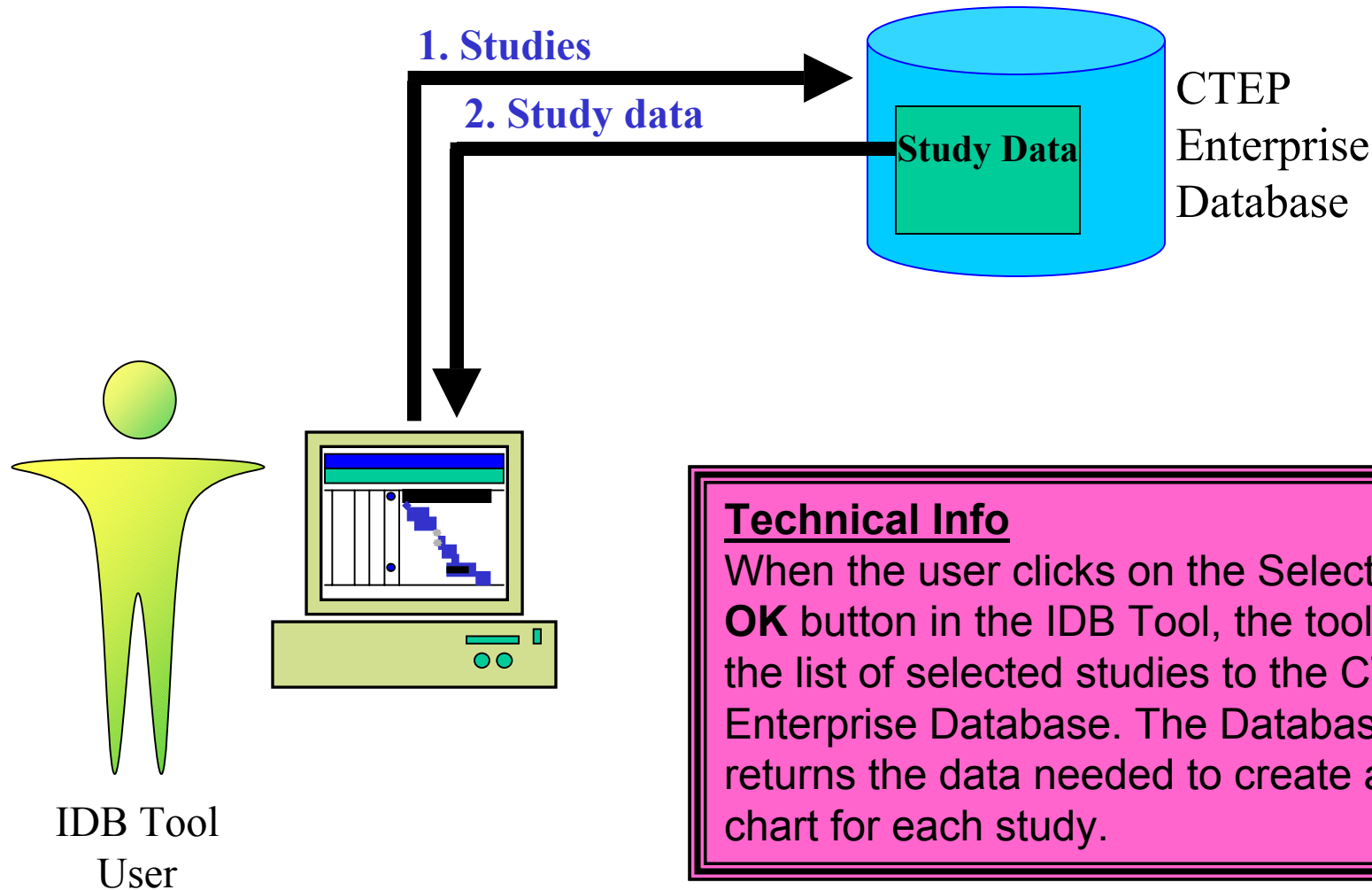
Tool Use

The user may click the **OK** button to build MS Project Gantt charts for all of the studies selected. After a brief delay, Gantt charts for the studies will be created in MS Project. The more studies you select, the longer the delay.

Creating a Gantt Chart



Creating a Gantt Chart



Technical Info

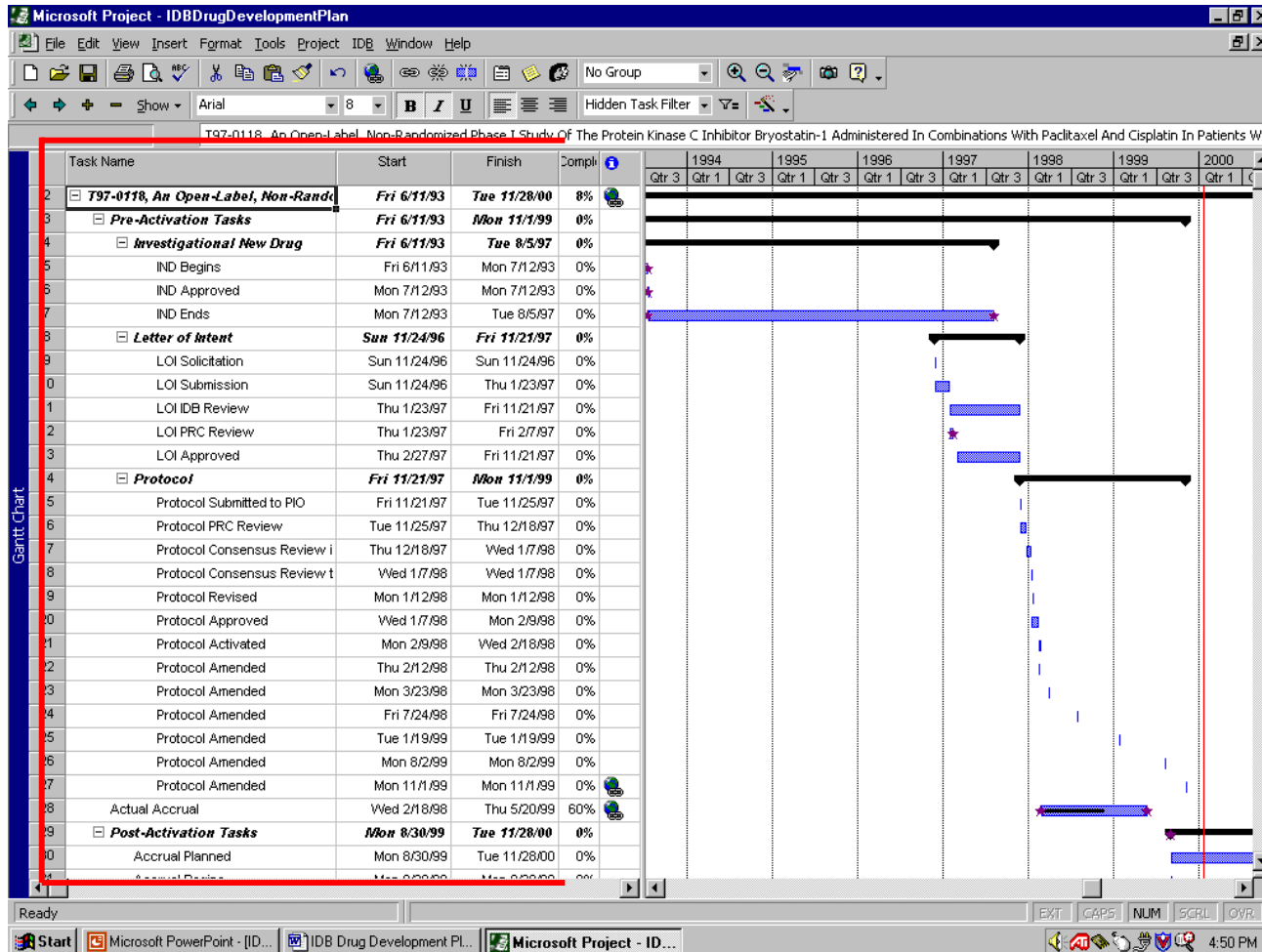
When the user clicks on the Select Studies **OK** button in the IDB Tool, the tool sends the list of selected studies to the CTEP Enterprise Database. The Database then returns the data needed to create a Gantt chart for each study.

Investigational Drug Branch Drug Development Plan Tool



Viewing the Gantt Chart

Reading a Gantt Chart






Tool Use

The left side of the Gantt chart shows the milestones and tasks within the study. It also shows the start and finish dates for each milestone.

Scenario Element:

The CRS now views the Gantt Chart of study T97-0118.

Reading a Gantt Chart

48	 CALGB-9430, Novel doublets in exten	Sun 1/1/84	Fri 7/9/99	8%
49	 Pre-Activation Tasks	Sun 1/1/84	Fri 6/12/98	0%
80	Actual Accrual	Sat 4/15/95	Thu 6/11/98	73%
81	 Post-Activation Tasks	Sat 4/15/95	Fri 7/9/99	0%

Tool Use

The tool displays each study's milestones and tasks in three main groups: Pre-Activation Tasks, Actual Accrual, and Post-Activation Tasks.

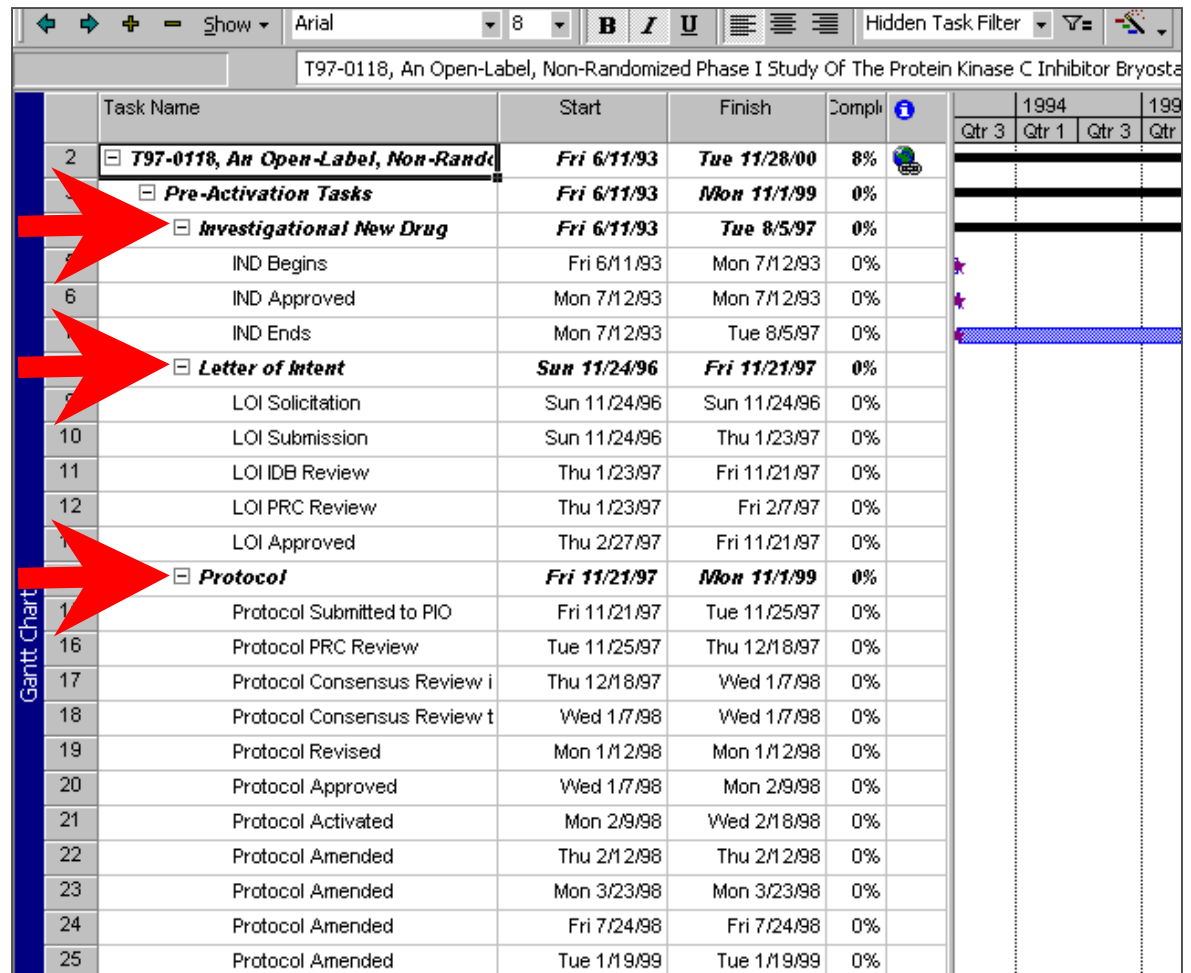
Tool Use

The user may open up or close a group of tasks by clicking on the plus sign or minus sign next to it. This will display all the tasks contained within that grouped or "rolled-up" task.

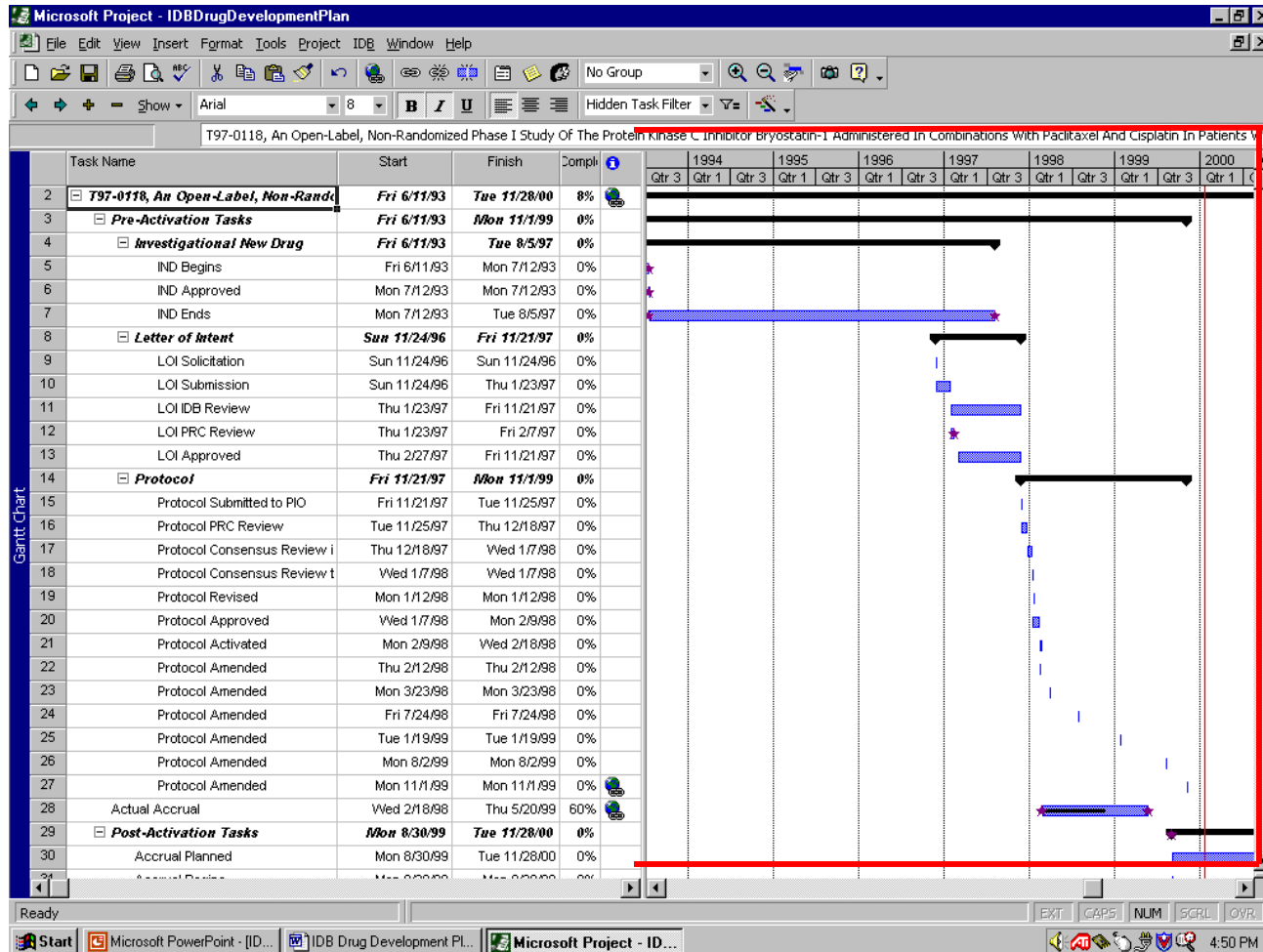
Reading a Gantt Chart

Tool Use

The Pre-Activation Tasks group contains three lower level groupings: *Investigational New Drug*, *Letter of Intent*, and *Protocol*. Each of these lower level groupings contains individual tasks and milestones that can be viewed or hidden by clicking on the plus or minus sign.



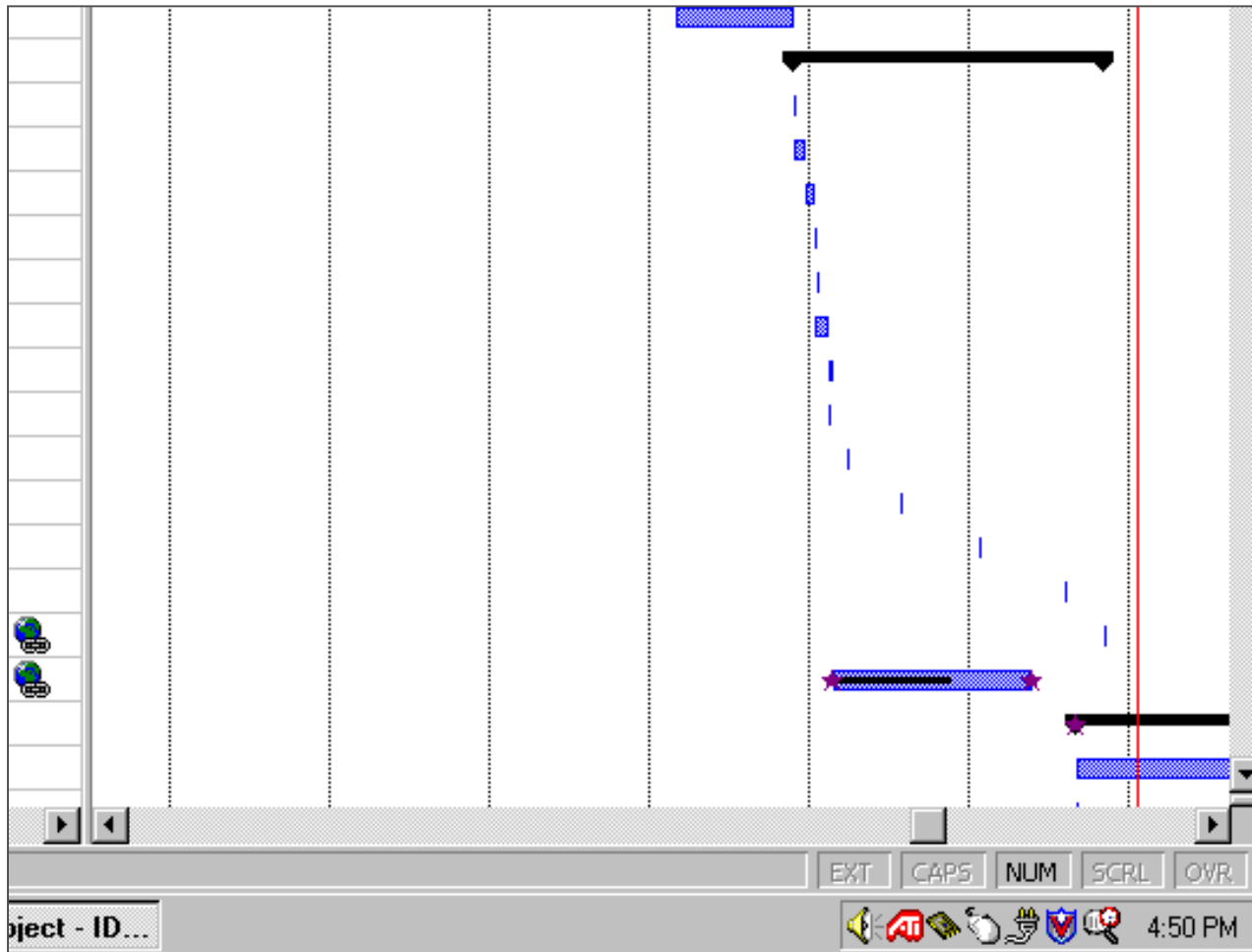
Reading a Gantt Chart



Tool Use

The right side of the Gantt chart shows the duration of each milestone or task. This is displayed by symbols and horizontal bars, with the timeline at the top.



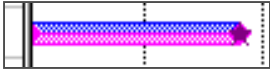



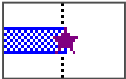
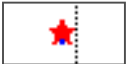
Reading a Gantt Chart



Tool Use

The bars and symbols on the IDB Drug Development Plan Tool Gantt chart are coded to convey specific meanings.

IDB Tool Gantt Chart Symbols

- Blue Bar**  This represents a task within a study (e.g., LOI Submitted, Protocol Approved).
- Black Bar with Black Diamond Ends**  This represents a summary task within a study (e.g., Pre-Activation Tasks, Protocol).
- Pink Bar below Blue Bar**  This represents a task with a start date and/or finish date prior to January 1, 1984. That is the earliest date that MS Project can display.
- Brown Bar**  This represents a task for which the database's start date is later than the database's finish date.
- Black Line in a Blue Bar**  This symbol is only used for the *Accrual Actual* task. The black line represents the percentage of the total desired accrual that was completed at the last accrual reporting date.
- Diamond or Very Short Blue Bar**  This is a task that takes place on a single day. For example, a Protocol Revision is approved on a specific date and would be represented by one of these symbols.
- Pink/Purple Star**  This represents a start date or a finish date that is based on a projection. This is done in cases where no actual database value is available for the date, so a projection from another known date is substituted. This symbol will usually appear at the end of a blue bar, or on top of a very short blue bar.
- Red Star**  This represents a date that has been overridden by a user. This may be done in cases where the user knows that a projected date or a database date is incorrect. This symbol will usually appear at the end of a blue bar, or on top of a very short blue bar.

Reading Notes in a Gantt Chart

Scenario Element:

The CRS reviews the study information pop-up, notes the IDB Monitors and sees that this study also involves the Agent Bryostatatin.

The screenshot shows the Microsoft Project application window titled "Microsoft Project - IDBDrugDevelopmentPlan". The menu bar includes File, Edit, View, Insert, Format, Tools, Project, IDB, Window, and Help. The toolbar contains various icons for file operations, editing, and project management. The task list table is as follows:

Task ID	Task Name	Start	Finish	Completion	Note Icon
2	T97-0118, An Open-Label, Non-Randomized Phase I Study Of The Protein Kinase C Inhibitor Bryostatatin-1 Administered In Combination	Fri 6/11/93	Tue 11/28/00	8%	Yes
3	Pre-Activation Tasks	Fri 6/11/93	Mon 11/1/99		No
4	Investigational New Drug	Fri 6/11/93	Tue 8/5/97		No
5	IND Begins	Fri 6/11/93	Mon 7/12/93	0%	No
6	IND Approved	Mon 7/12/93	Mon 7/12/93	0%	No
7	IND Ends	Mon 7/12/93	Tue 8/5/97	0%	No
8	Letter of Intent	Sun 11/24/96	Fri 11/21/97	0%	No
9	LOI Solicitation	Sun 11/24/96	Sun 11/24/96	0%	No
10	LOI Submission	Sun 11/24/96	Thu 1/23/97	0%	No

A red arrow points to the note icon (a small document with a speech bubble) next to the task "T97-0118, An Open-Label, Non-Randomized Phase I Study Of The Protein Kinase C Inhibitor Bryostatatin-1 Administered In Combination". A pop-up window titled "Document info" is displayed, containing the following text:

Document info
 Monitor: Anthony Murgo
 Monitor: Susan Arbuck
 Agent: BRYOSTATIN 339555
 Disease: Solid tumor NOS
 PI: Gary Schwartz
 Inst.: Memorial Sloan Kettering
 Cancer Center

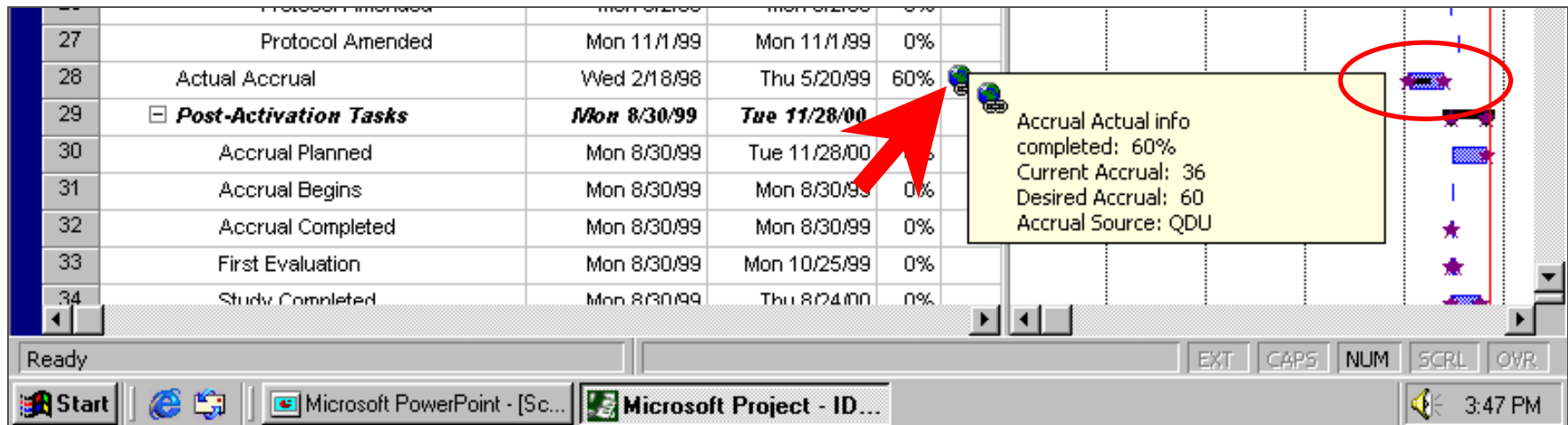
Tool Use

This symbol indicates that a note of some kind is attached to the task. The user may read the note by placing the cursor over this symbol but not clicking the mouse. The note next to the study title contains general study information.

Reading Notes in a Gantt Chart

Scenario Element:

The CRS reviews the study's accrual information.



Tool Use

The note next to the Actual Accrual task contains accrual information, including the most recent source of accrual reporting. The bar next to this task contains a black progress bar that shows the percentage of planned accrual completed.

Investigational Drug Branch Drug Development Plan Tool



Adding Notes and User-Defined Tasks to Gantt Charts

Annotating Tasks in a Gantt Chart

Scenario Element:

The CRS needs to add a note about patient responses to the Gantt chart for study T97-0118. This note will be seen by the IDB Monitor the next time he or she charts the study. The CRS decides to add the note to the “Accrual Begins” task in the Post-Activation Tasks section of the Gantt chart.

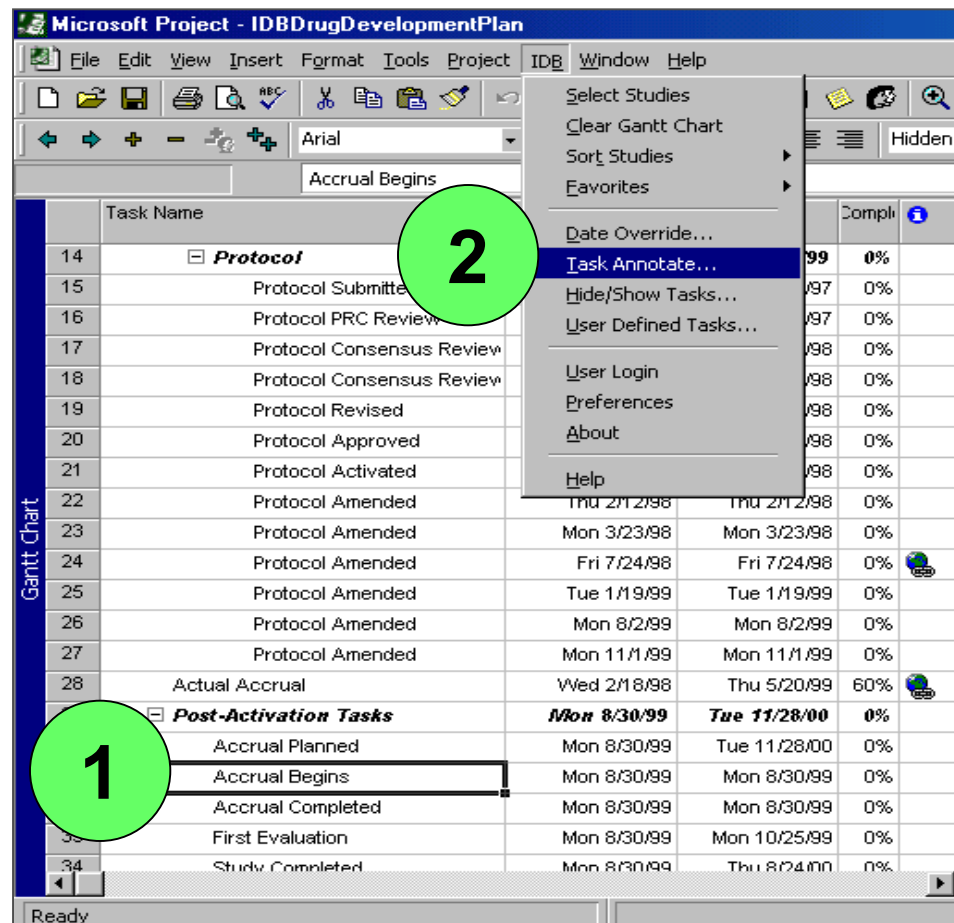
Annotating Tasks in a Gantt Chart

Scenario Element:

The CRS first selects the “Accrual Begins” cell in the Gantt Chart. Next, the CRS selects the Task Annotate command from the IDB menu.

Tool Use

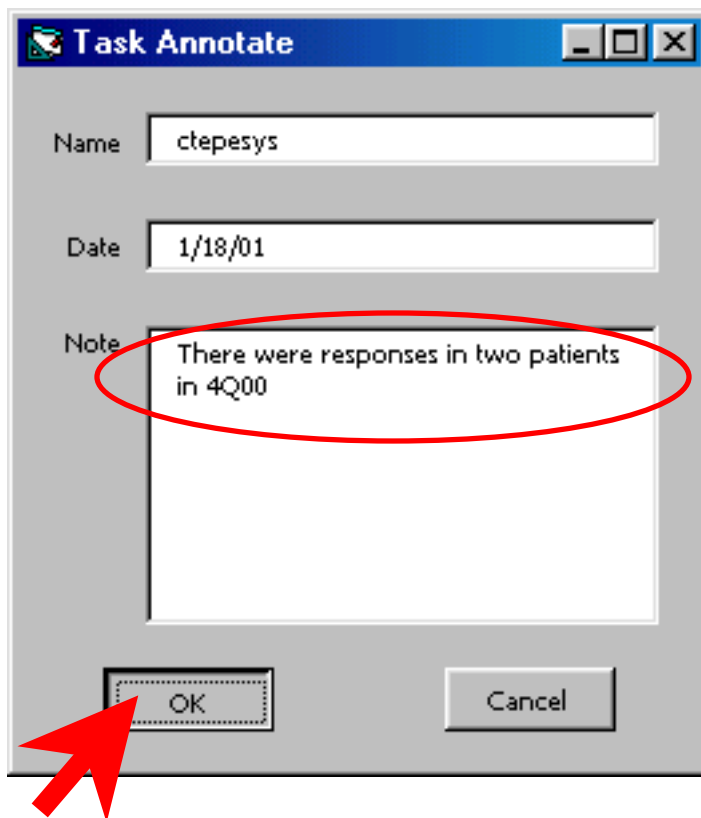
The **Task Annotate** feature allows users to attach notes to any task displayed in the Gantt chart. The notes will be saved to a special table in the CTEP Enterprise Database and remain accessible to any other user who charts the study using the IDB Drug Development Plan. The system also records and displays the date and user name associated with the last annotation.



Annotating Tasks in a Gantt Chart

Scenario Element:

When the Task Annotate dialog box appears, the CRS types “There were responses in two patients in 4Q00” and clicks OK.



The screenshot shows the 'Task Annotate' dialog box with the following fields:

- Name: ctepesys
- Date: 1/18/01
- Note: There were responses in two patients in 4Q00

The 'Note' field is highlighted with a red oval, and a red arrow points to the 'OK' button.

Tool Use

The **Task Annotate** dialog box allows the user to enter a short note of up to 255 characters in the CTEP Enterprise Database. The note will be accessible by any user who charts the study. The user need not fill out the Name and Date fields in this dialog box. They are populated with the user's ID and the current date.

Annotating Tasks in a Gantt Chart

Technical Info

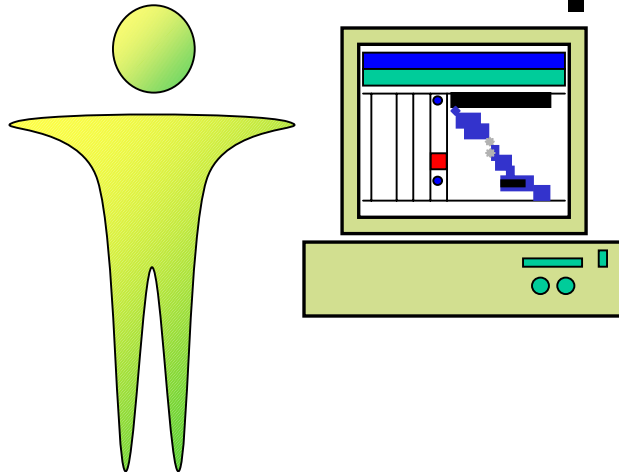
Notes are automatically saved in the CTEP Enterprise Database. Other users may view them as soon as they are entered.

Add Notes

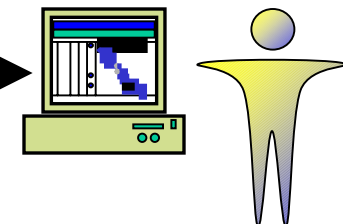
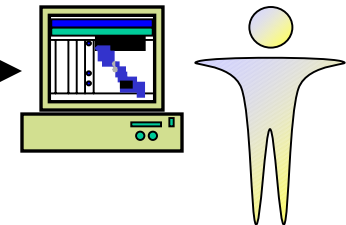
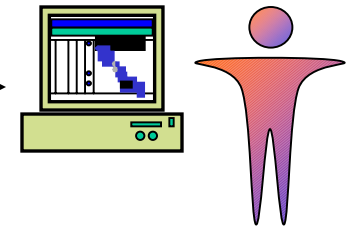
Study Data

CTEP
Enterprise
Database

**Other Users
Chart Study
(Includes
Notes)**





IDB Tool
User



Annotating Tasks in a Gantt Chart

Scenario Element:

The CRS verifies that a note symbol now appears next to the “Accrual Begins” task in the Gantt Chart.

27	Protocol Amended	Mon 11/1/99	Mon 11/1/99	0%	
28	Actual Accrual	Wed 2/18/98	Thu 5/20/99	60%	
29	<input type="checkbox"/> Post-Activation Tasks	Mon 8/30/99	Tue 11/28/00	0%	
30	Accrual Planned	Mon 8/30/99	Tue 11/28/00	0%	
31	Accrual Begins	Mon 8/30/99	Mon 8/30/99	0%	
32	Accrual Completed	Mon 8/30/99	Mon 8/30/99		
33	First Evaluation	Mon 8/30/99	Mon 10/25/99		
34	Study Completed	Mon 8/30/99	Thu 8/24/00	0%	

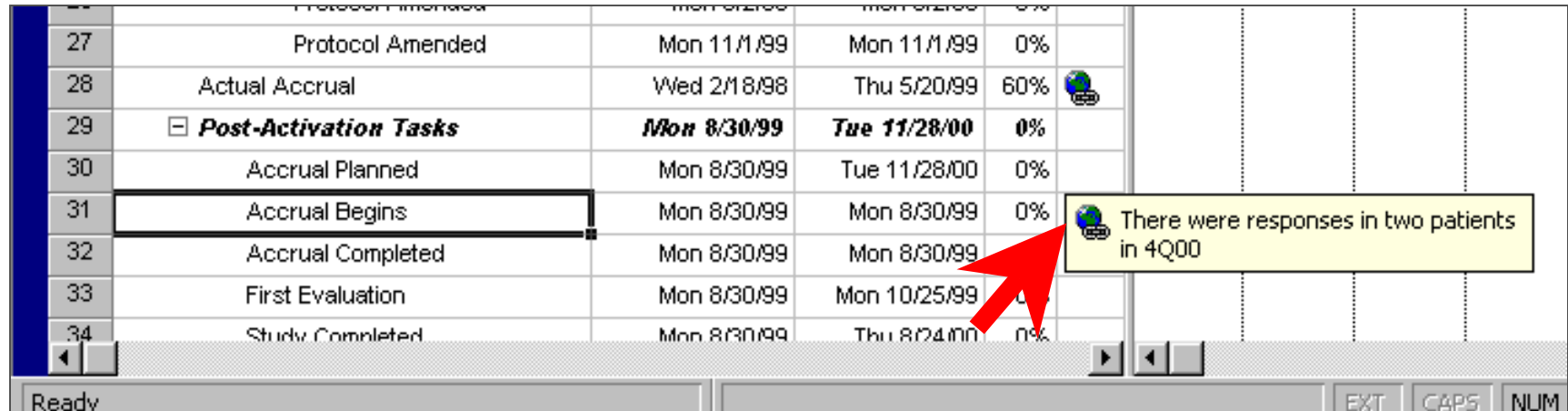
A red arrow points to the note icon next to the 'Accrual Begins' task (row 31).

Ready | EXT | CAPS | NUM

Annotating Tasks in a Gantt Chart

Scenario Element:

The CRS reads the note by hovering the mouse over the icon.



Tool Use

The user may view the note contents by hovering the mouse over the hyperlink symbol. This method displays the note text, but does not show the user name and date. If the user clicks on the hyperlink symbol, the following message will appear: "Cannot open the specified file." This is not an error, and the user may simply click the **OK** button to return to the Gantt chart.

Adding User-Defined Tasks to a Gantt Chart

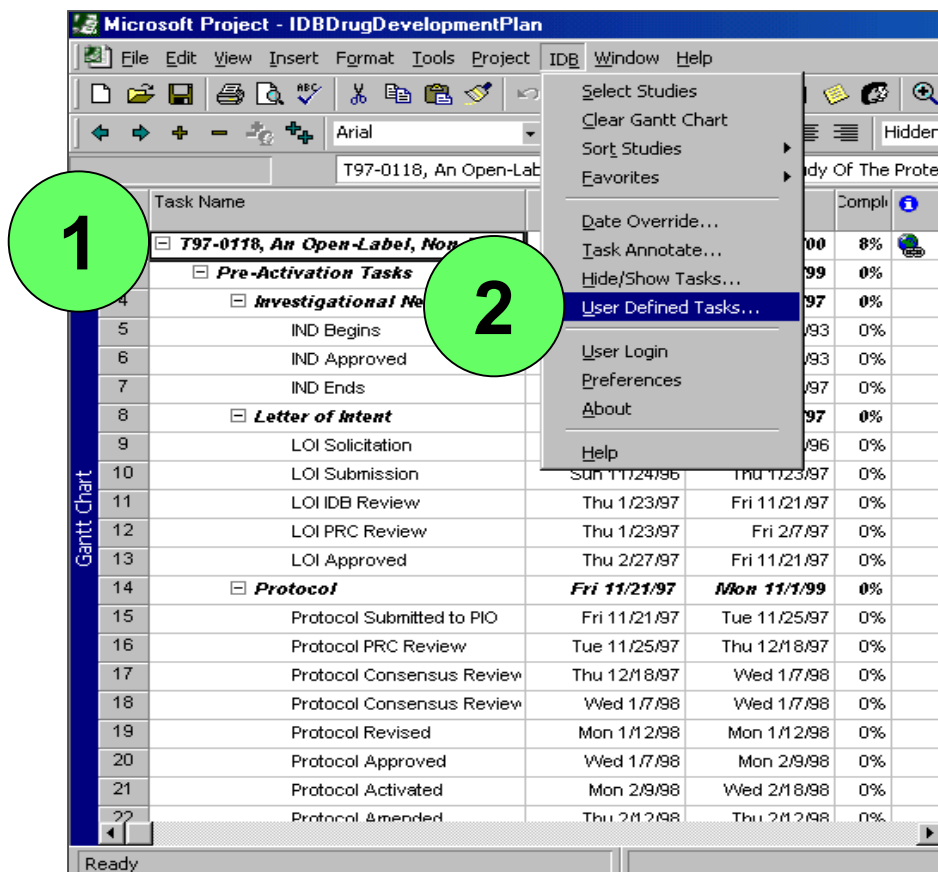
Scenario Element:

The CRS needs to add a user-defined task called “Solicit Phase II Study” to the Gantt chart for study T97-0118. This task will be seen by the IDB Monitor the next time he or she charts the study. The CRS decides to add the task after the “Actual Accrual” task in the Gantt chart.

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS first selects any task in study T97-0118. Then the CRS selects the “User Defined Tasks...” command from the IDB menu.

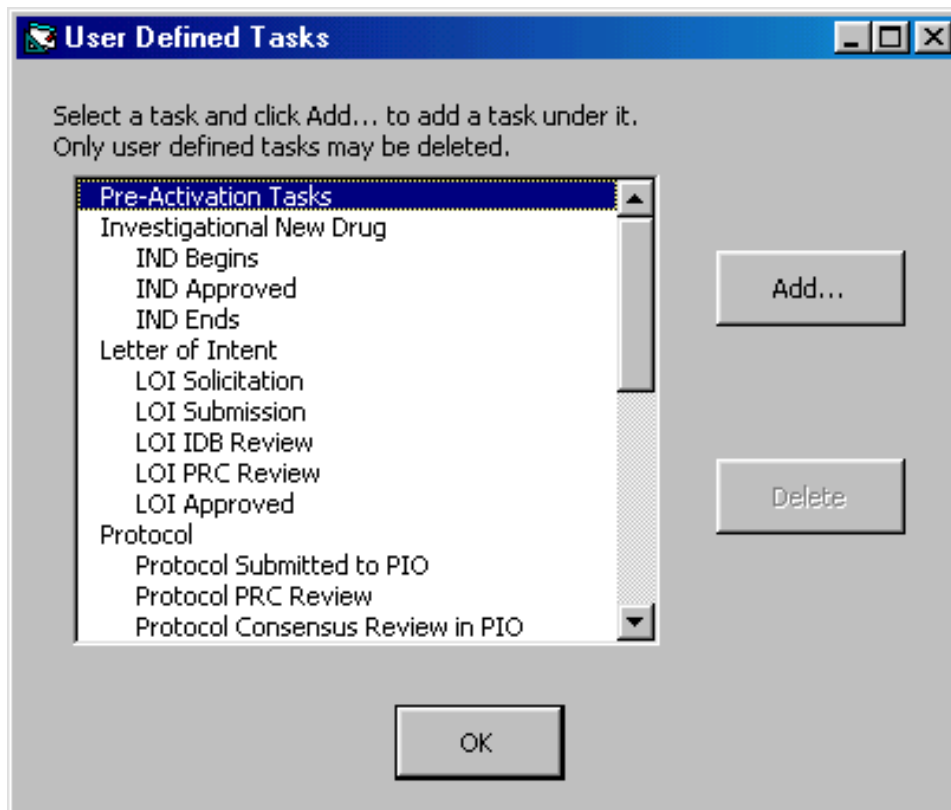


Tool Use

The user may define one or more tasks that are not normally part of a study. The tasks will be displayed as part of the study's Gantt chart whenever any user creates the chart.

*To create a User-Defined Task in a study, a Gantt chart of that study must currently be displayed on the screen. The user should click on the name of any task within the study and then click on the **User-Defined Tasks** option located on the **IDB** drop-down menu.*

Adding User-Defined Tasks to a Gantt Chart



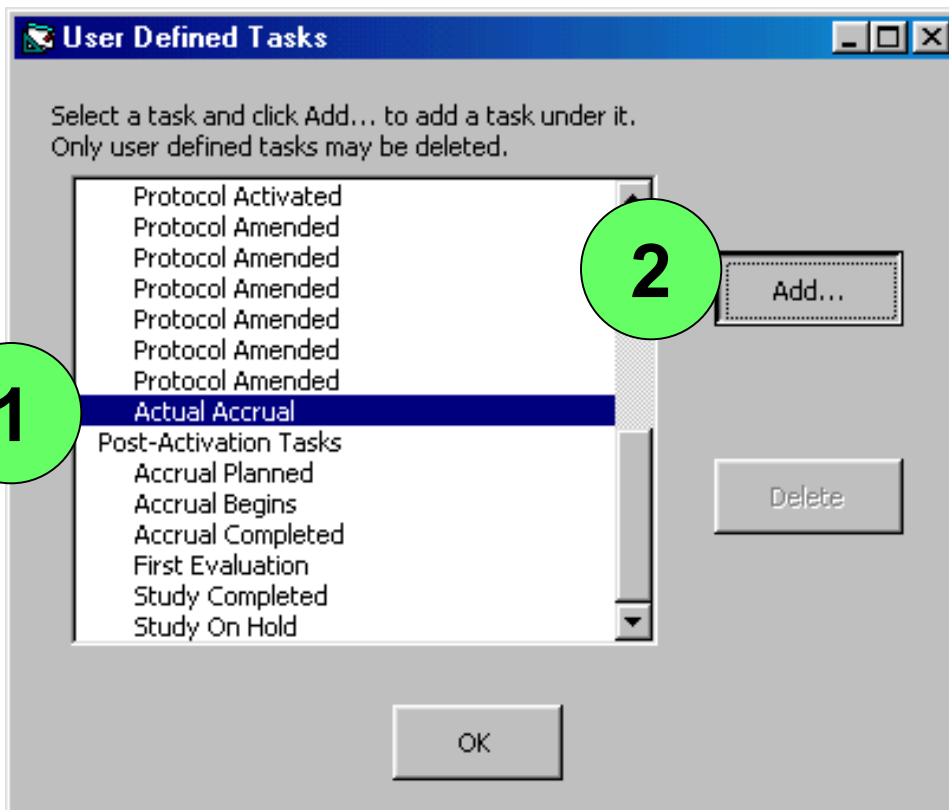
Tool Use

*The **User-Defined Tasks** dialog box contains a list of all the tasks in the study. The user may scroll down through the list to find the correct spot for the user-defined task.*

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS inserts a user-defined task below the existing Actual Accrual task.



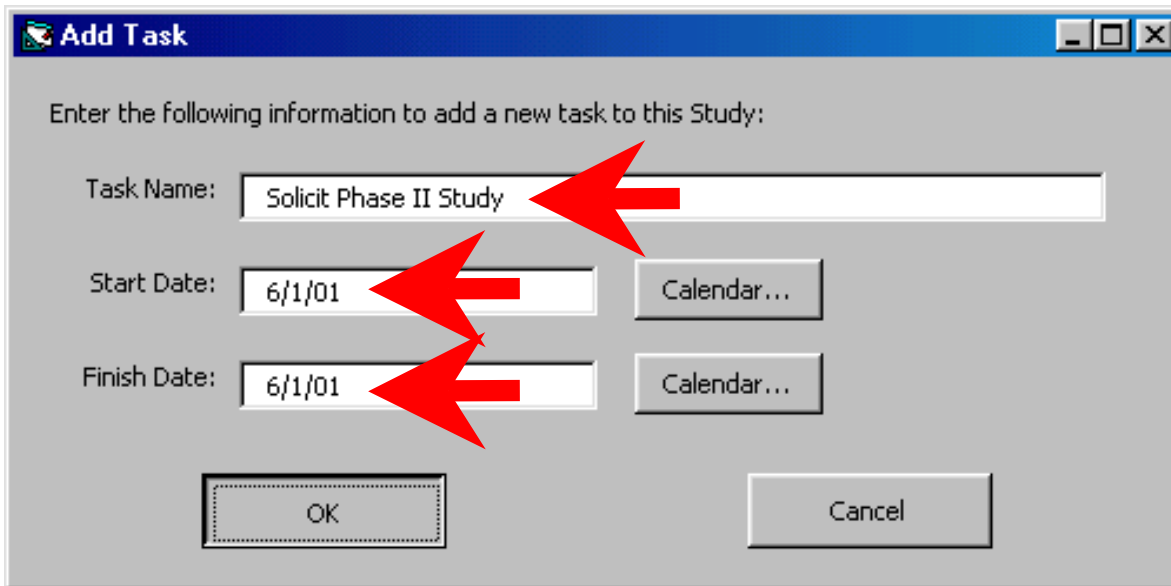
Tool Use

The user must click on an existing task that is located just above the desired insertion location of the User-Defined Task. When the correct existing task is highlighted, the user should click on the **Add** button. This will open the Add Task dialog box.

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS titles the task “Solicit Phase II Study” and types in the start and stop dates for the new task.



Tool Use

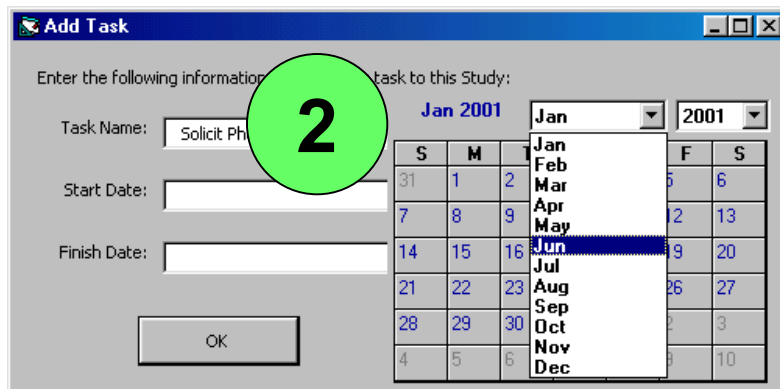
*The name of the new user-defined task should be typed in the **Task Name** box.*

*The user must enter both a **Start Date** and a **Finish Date** for the User-Defined Task. MS Project cannot place the task in a Gantt chart without both a Start Date and a Finish Date. A task may have the same Start Date and Finish Date.*

Adding User-Defined Tasks to a Gantt Chart

Tool Use

The user may also click on the **Calendar** button to access a calendar that may be used to find a Start Date or a Finish Date.



Add Task

Enter the following information to add a new task to this Study:

Task Name: Solicit Ph

Start Date:

Finish Date:

Jan 2001

Jan

Feb

Mar

Apr

May

Jun

Jul

Aug

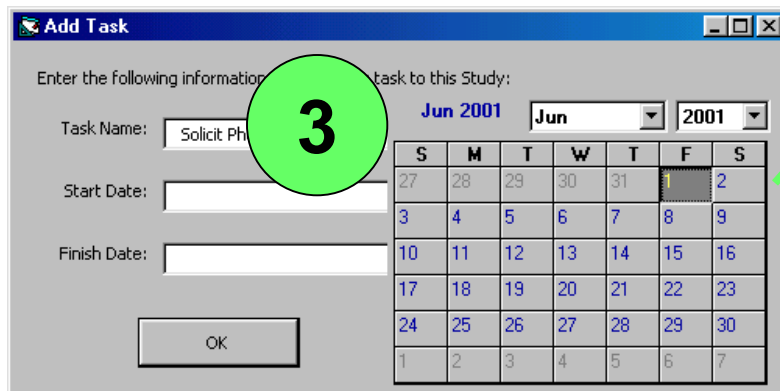
Sep

Oct

Nov

Dec

OK



Add Task

Enter the following information to add a new task to this Study:

Task Name: Solicit Ph

Start Date:

Finish Date:

Jun 2001

Jun

2001

S M T W T F S

27 28 29 30 31 1 2

3 4 5 6 7 8 9

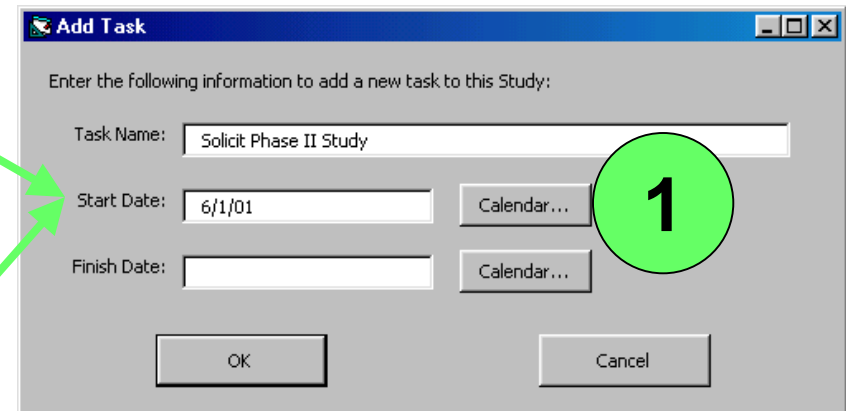
10 11 12 13 14 15 16

17 18 19 20 21 22 23

24 25 26 27 28 29 30

1 2 3 4 5 6 7

OK



Add Task

Enter the following information to add a new task to this Study:

Task Name: Solicit Phase II Study

Start Date: 6/1/01

Finish Date:

Calendar...

Calendar...

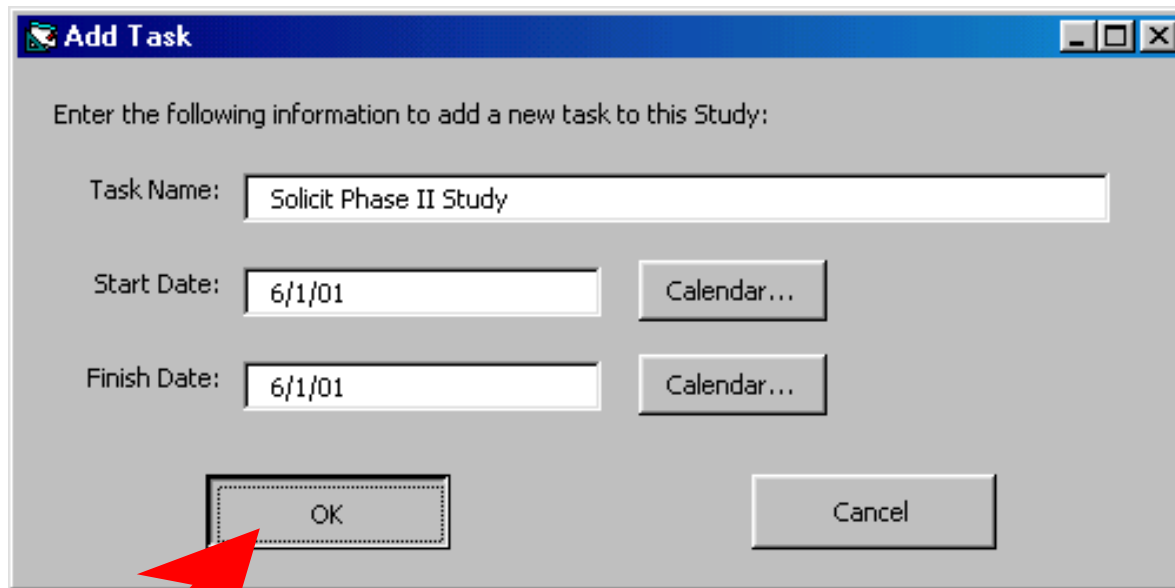
OK

Cancel

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS clicks **OK** to save the user-defined task to the database.



Enter the following information to add a new task to this Study:

Task Name: Solicit Phase II Study

Start Date: 6/1/01 Calendar...

Finish Date: 6/1/01 Calendar...

OK Cancel

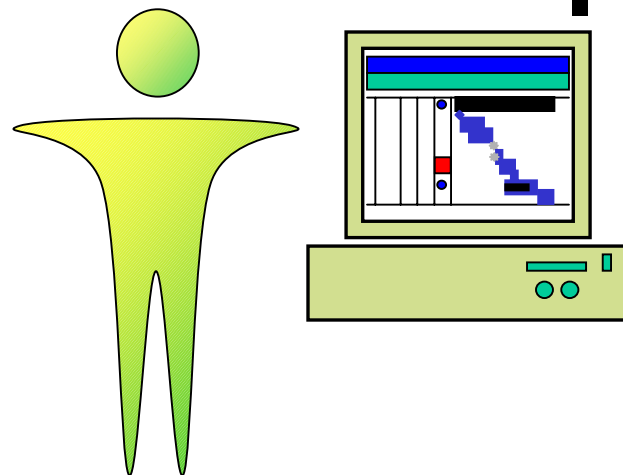
Tool Use

*When all information for the User-Defined Task has been entered, the **OK** button will save the new task, close the **Add Task** dialog box and return the user to the **User-Defined Task** dialog box. The **Cancel** button will close the **Add Task** dialog box without saving the new task.*

Adding User-Defined Tasks to a Gantt Chart

Technical Info

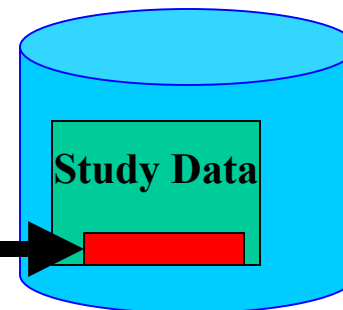
User-defined tasks are automatically saved in the CTEP Enterprise Database. Other users may view them as soon as they are entered.



IDB Tool
User

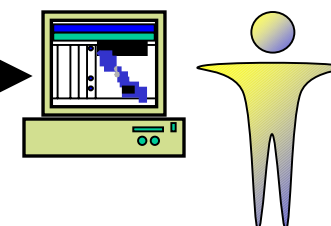
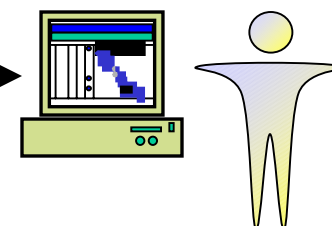
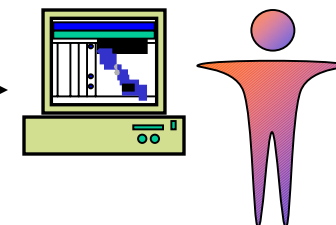


Add Tasks



CTEP
Enterprise
Database

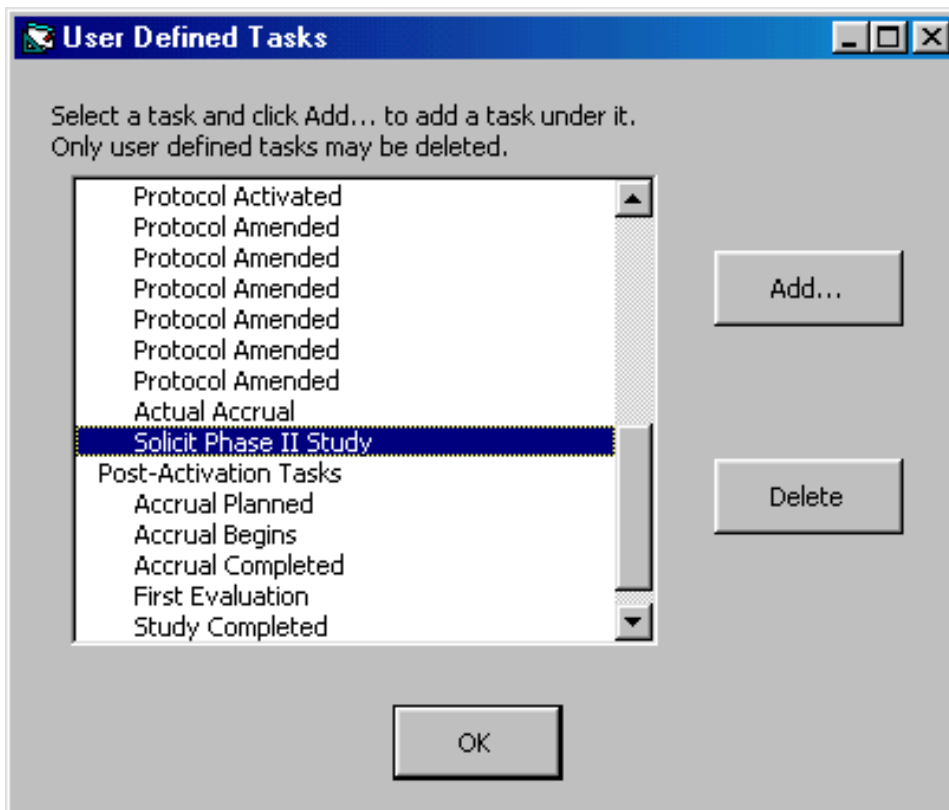
Other
Users
Chart
Study
(Includes
User-
Defined
Tasks)



Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS verifies that the new task is displayed in the User-Defined Task window and clicks OK to return to the Gantt Chart display.



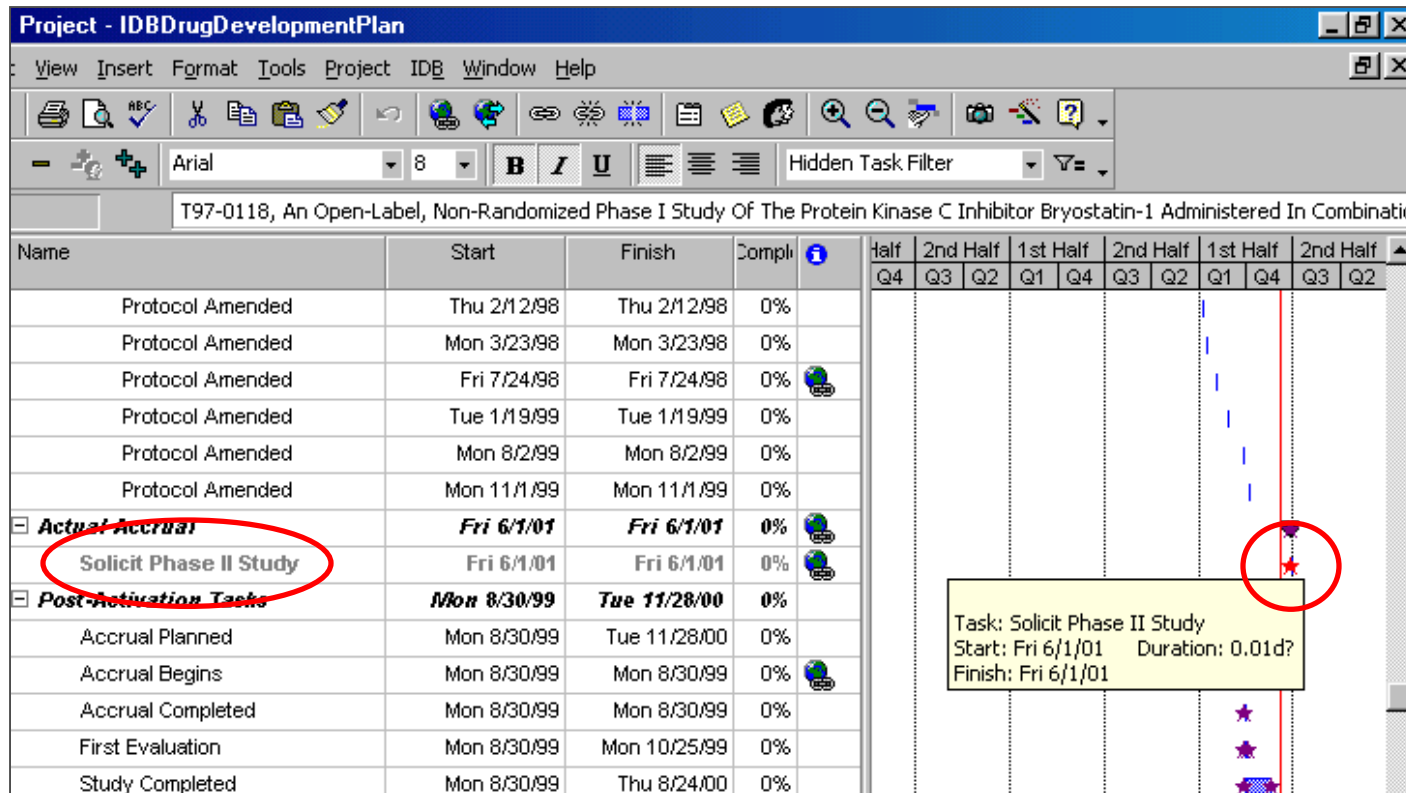
Tool Use

*The new task now appears in the desired location in the **User-Defined Task** window. The user may add another task by following the same procedure again. The **OK** button will close the **User-Defined Task** dialog box and return the user to the MS Project Gantt chart window.*

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS verifies that the new task and its dates now appear in the Gantt Chart.



Tool Use

The names of user-defined tasks appear in gray text. User-defined dates appear in the chart as red stars.

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS adds the following note to the new task: “Solicit for Phase II trial in with a date of June 2001.”

1 Select the task 'Solicit Phase II Study' in the task list.

2 Right-click on the task and select 'Task Annotate...' from the context menu.

3 In the 'Task Annotate' dialog box, enter the note: 'Solicit for Phase II trial in with a date of June 2001'.

4 The Gantt chart shows the task with the note displayed in a tooltip.

Task Name	Start Date	End Date	Progress
Protocol Amended	Mon 11/1/99	Mon 11/1/99	0%
Actual Accrual	Fri 6/1/01	Fri 6/1/01	0%
Solicit Phase II Study	Fri 6/1/01	Fri 6/1/01	0%
Post-Activation Tasks	Mon 8/30/99	Tue 11/28/00	0%
Accrual Planned	Mon 8/30/99	Tue 11/28/00	0%
Accrual Begins	Mon 8/30/99	Mon 8/30/99	0%

Investigational Drug Branch Drug Development Plan Tool



Saving and Printing Gantt Charts

Saving a Gantt Chart as a Favorite

Scenario Element:

The CRS decides that she or he may need to view the Gantt chart for this study a number of time in the near future. The CRS also decides that a printout of the chart would be handy at an upcoming meeting.

Saving a Gantt Chart as a Favorite

Scenario Element:

The CRS chooses to save this study as one of his or her “Favorites” in order to chart it again easily in the future.

Microsoft Project - IDBDrugDevelopmentPlan

File Edit View Insert Format Tools Project IDB Window Help

Task Name

T97-0118, An Open-Label, Non-Rand...

Pre-Activation Tasks

Investigational New Drug

IND Begins

IND Approved

IND Ends

Letter of Intent

LOI Solicitation

LOI Submission

LOI IDB Review

LOI PRC Review

LOI Approved

Protocol

Protocol Submitted to PIO

Protocol PRC Review

7/28/00 8%

1/1/99 0%

8/5/97 0%

7/12/93 0%

7/12/93 0%

Mon 7/12/93 Tue 8/5/97 0%

Sun 11/24/96 Fri 11/21/97 0%

Sun 11/24/96 Sun 11/24/96 0%

Sun 11/24/96 Thu 1/23/97 0%

Thu 1/23/97 Fri 11/21/97 0%

Thu 1/23/97 Fri 2/7/97 0%

Thu 2/27/97 Fri 11/21/97 0%

Fri 11/21/97 Mon 11/1/99 0%

Fri 11/21/97 Tue 11/25/97 0%

Tue 11/25/97 Thu 12/18/97 0%

Tool Use

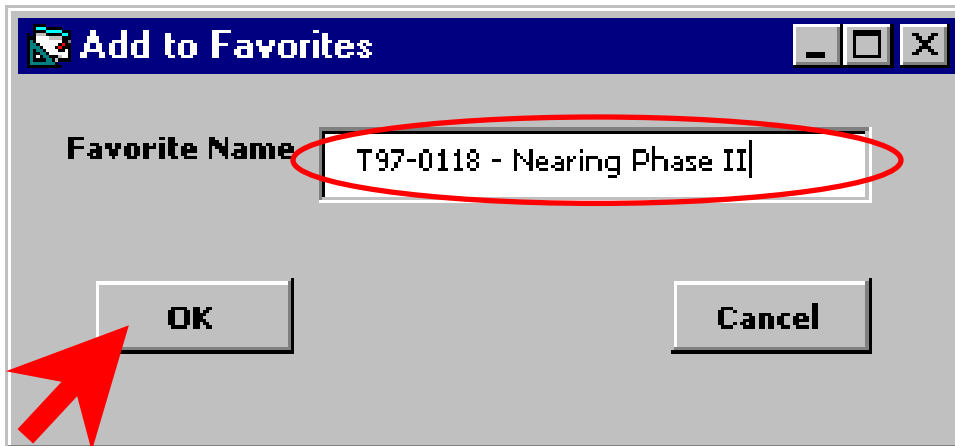
To save one or more studies as Favorites, the user should highlight the title of each study. If multiple studies are on the screen, the user can hold down the CTL key while clicking on study titles.

The user should then select the **Add Favorites** command from **Favorites** item on the **IDB** menu.

Saving a Gantt Chart as a Favorite

Scenario Element:

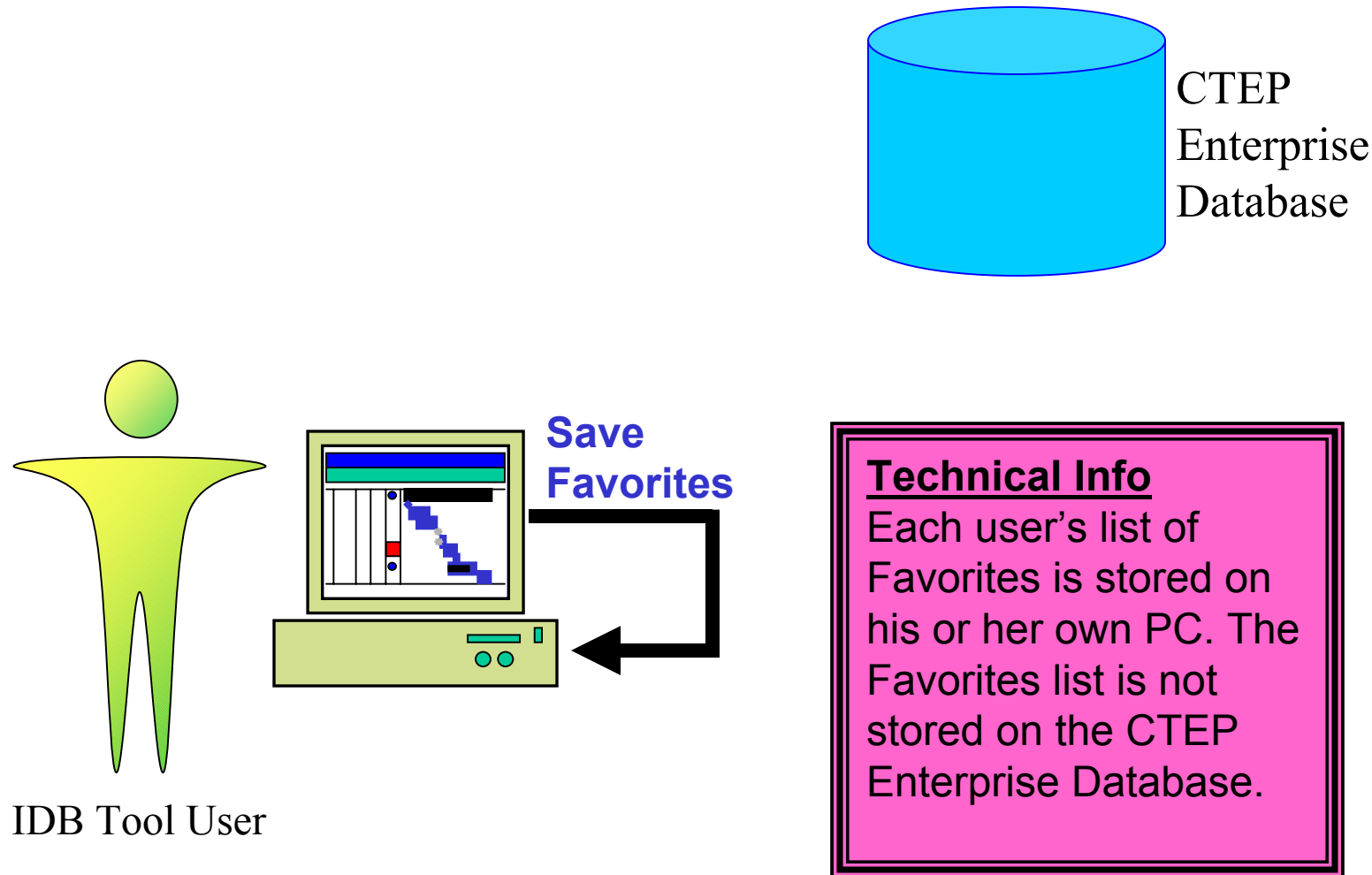
The CRS names this Favorite in a way that makes it quickly and easily recognizable.



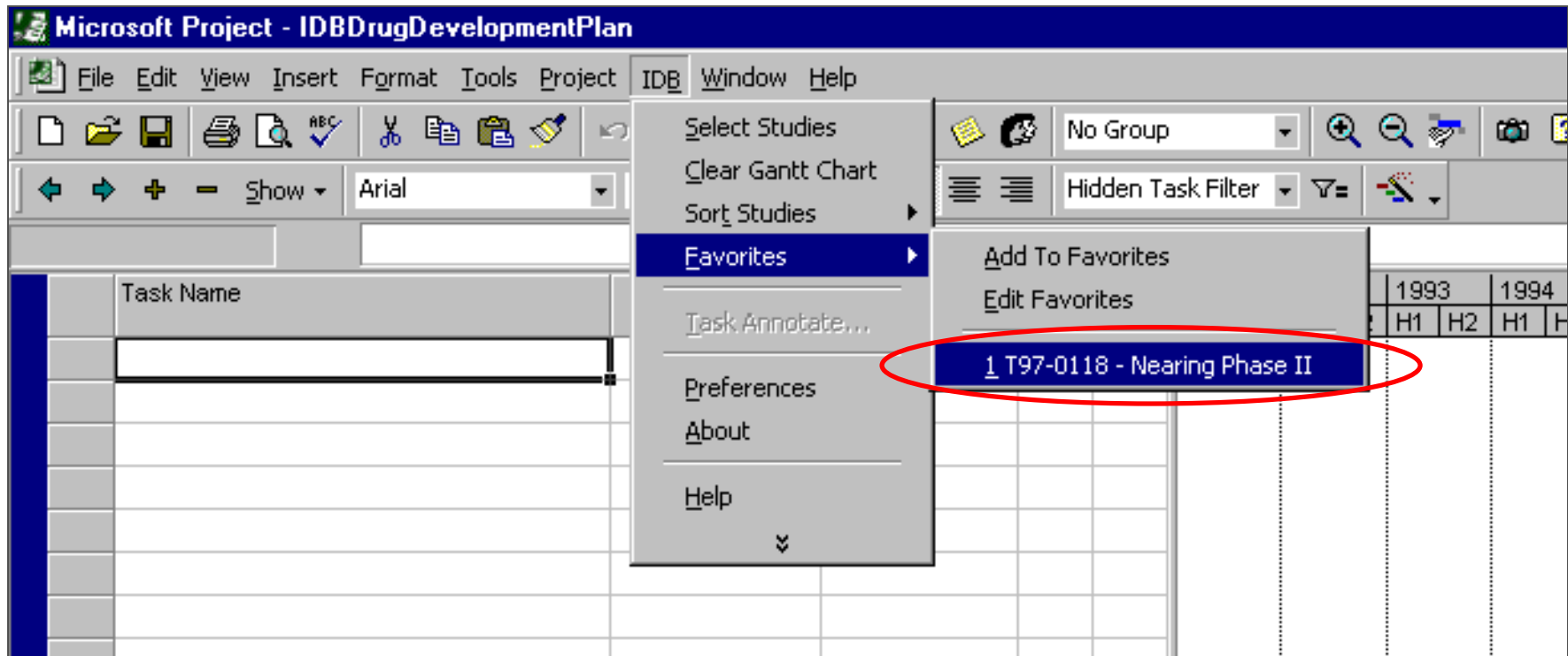
Tool Use

The user may give the Favorite any name he or she wishes and then click OK.

Saving a Gantt Chart as a Favorite



Saving a Gantt Chart as a Favorite

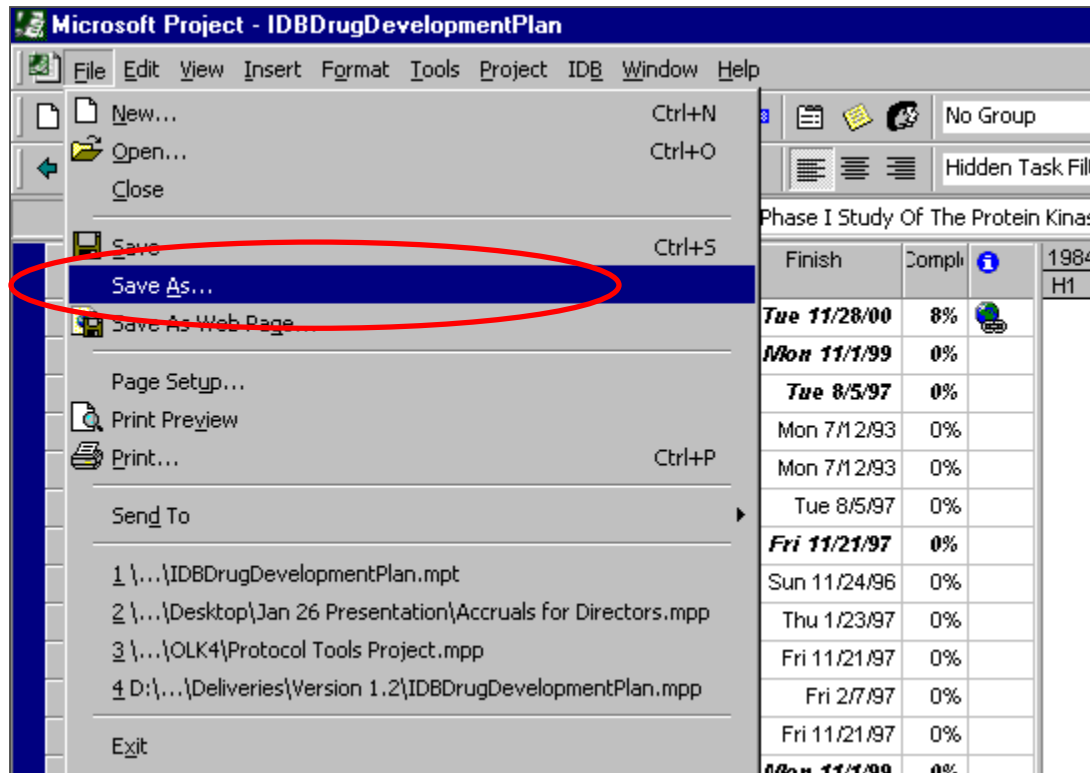


Tool Use

Once a Favorite has been named and saved, it appears on the favorites list. A saved Favorite may be re-charted with the latest data just by clicking on its name.

*Each user may have a maximum of 10 Favorites. Favorites may be deleted by using the **Edit Favorites** command.*

Saving a Gantt Chart as a File



Tool Use

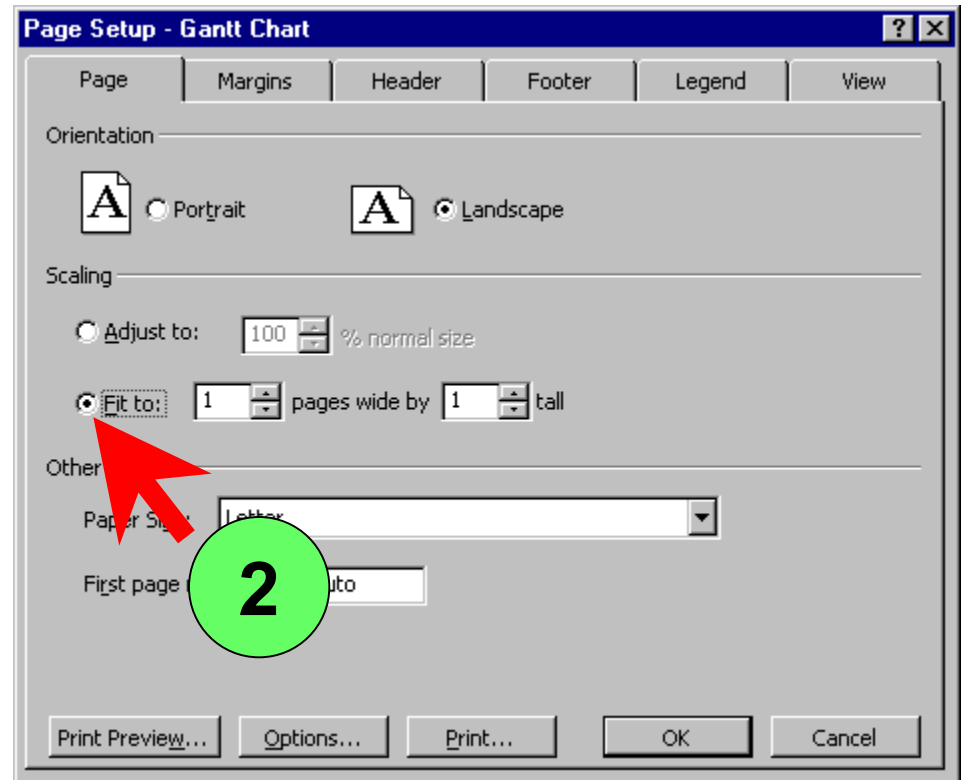
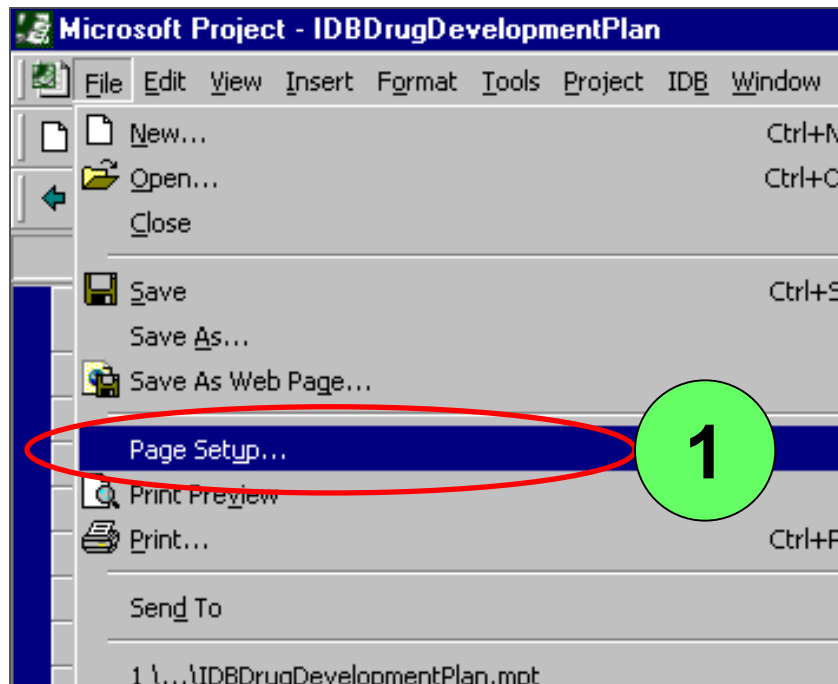
*The user may prefer to save today's view of the Gantt chart. The user may have formatted it in a specific way, or it may show data likely to change in the near future. In this case, the user may save the chart by using the **Save As** command from the **File** menu. This feature works just like any other Windows product.*

*The user must use **Save As** rather than **Save**. The IDB Drug Development Plan Tool will not allow the user to simply save the file, since that would change how the tool functions.*

Printing a Gantt Chart

Scenario Element:

The CRS sets up the Gantt chart so that it will print on a single page.



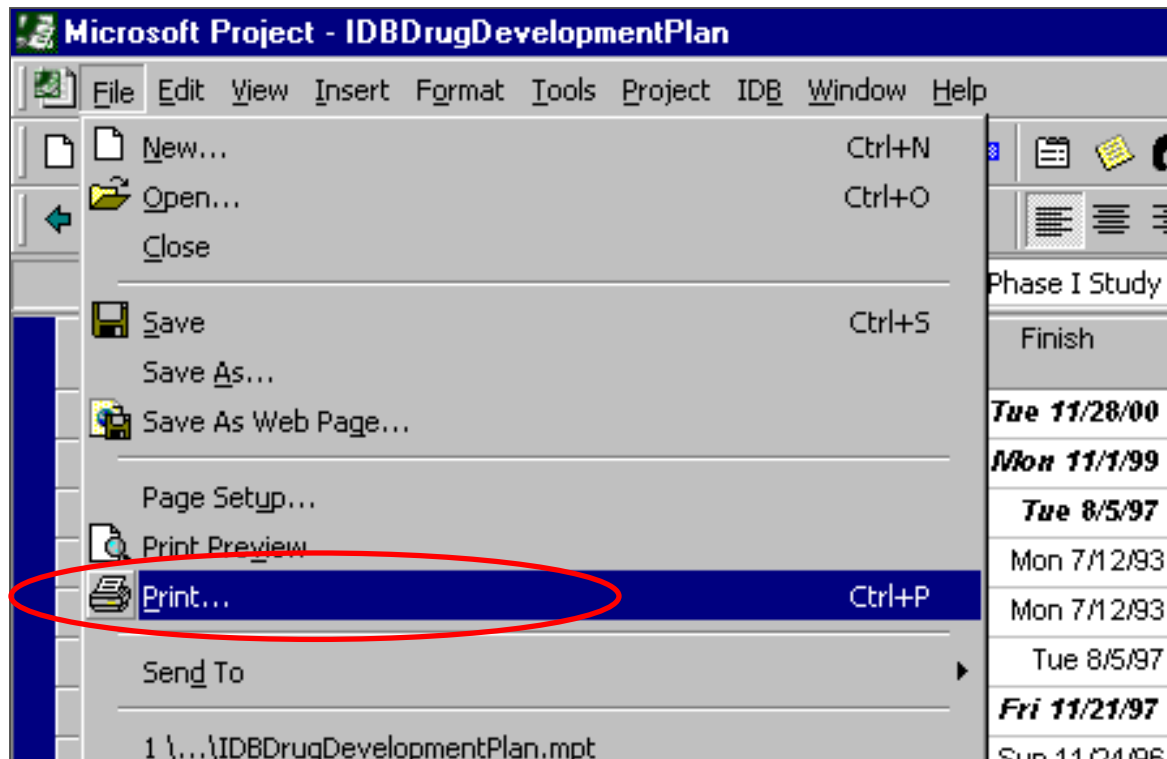
Tool Use

The user may set up a Gantt chart to print on a single page at the Page Setup dialog box.

Printing a Gantt Chart

Scenario Element:

The CRS prints the Gantt chart of study T97-0118 by using MS Project's regular print functions.



Tool Use

The user may print a Gantt chart by using the **Print** command on the **File** menu.

Investigational Drug Branch Drug Development Plan Tool

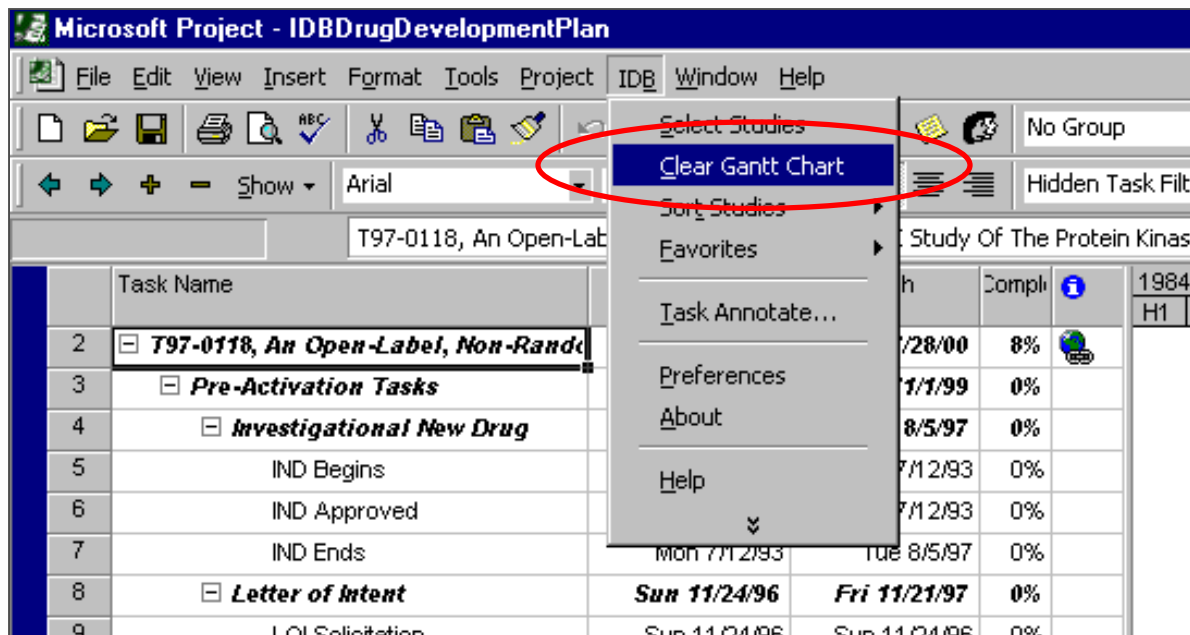


Clearing the Gantt Chart And Searching by Keyword

Clearing the Gantt Chart

Scenario Element:

The CRS is done with study T97-0118 and clears its Gantt chart from the screen.



Tool Use

*The user may clear a Gantt chart from the screen by choosing the **Clear Gantt Chart** command from the **IDB** menu.*

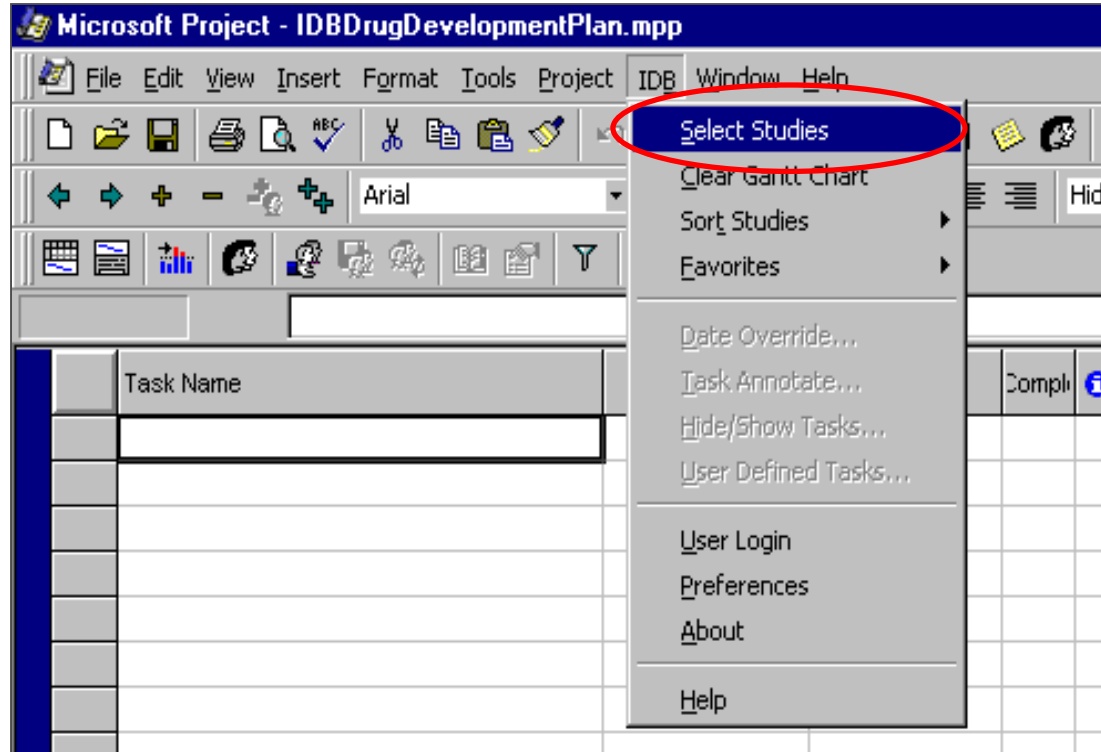
Technical Info

Clearing the Gantt chart does not affect any of the information that has been saved. It merely clears the Gantt chart from the user's screen.

Searching for Studies by Keyword

Scenario Element:

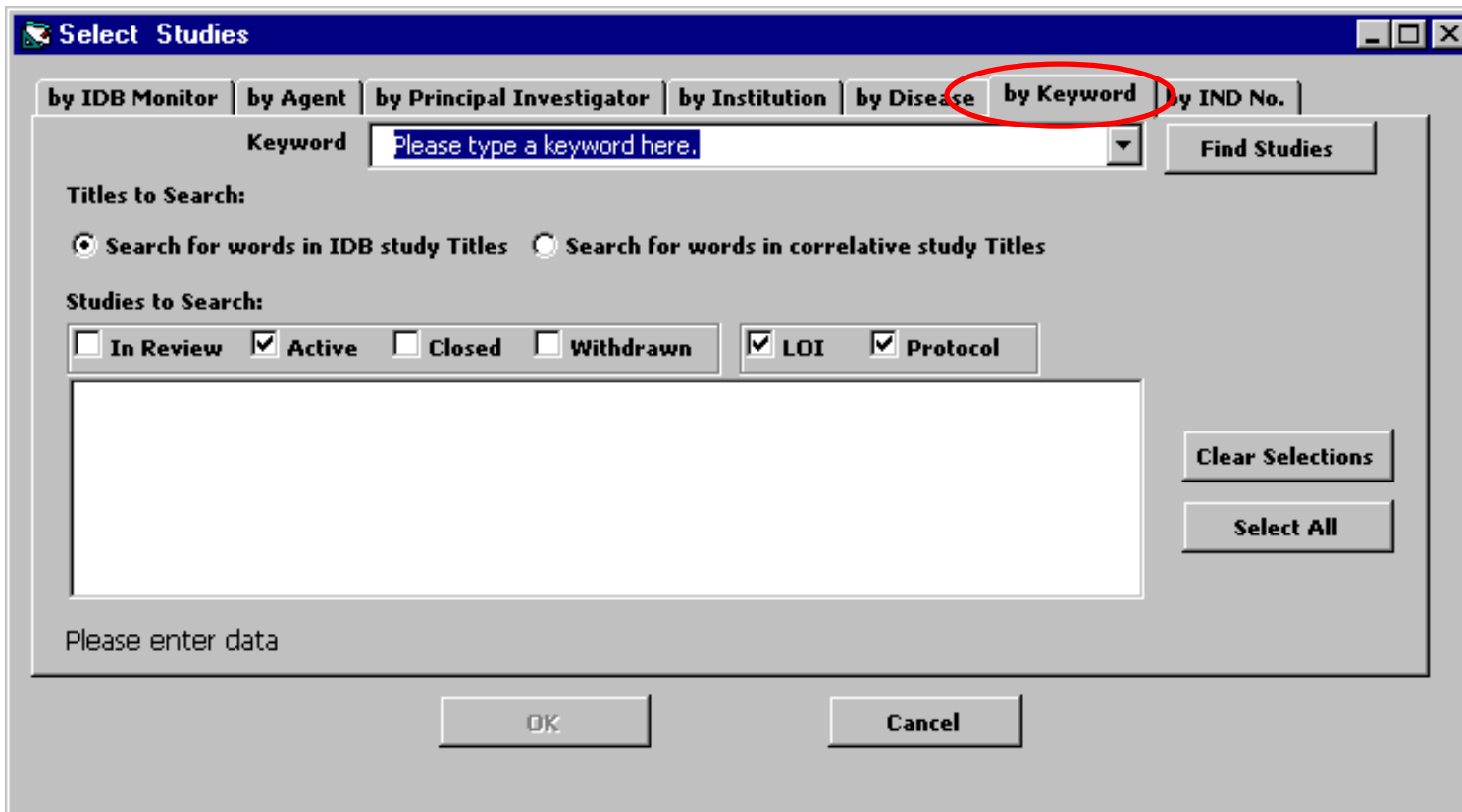
The CRS decides to carry out a search for imaging-related correlative studies that has been requested recently. The CRS chooses the “Select Studies” command.



Searching for Studies by Keyword

Scenario Element:

At the Select Studies dialog box, the CRS clicks on the “by Keyword tab.



The screenshot shows the 'Select Studies' dialog box. The 'by Keyword' tab is selected and circled in red. The 'Keyword' field contains the placeholder text 'Please type a keyword here.' and has a dropdown arrow. To the right of the field is a 'Find Studies' button. Below the field, under 'Titles to Search:', there are two radio buttons: 'Search for words in IDB study Titles' (selected) and 'Search for words in correlative study Titles'. Under 'Studies to Search:', there are two groups of checkboxes. The first group includes 'In Review' (unchecked), 'Active' (checked), 'Closed' (unchecked), and 'Withdrawn' (unchecked). The second group includes 'LOI' (checked) and 'Protocol' (checked). Below these checkboxes is a large empty text area. To the right of the text area are two buttons: 'Clear Selections' and 'Select All'. At the bottom of the dialog are 'OK' and 'Cancel' buttons. The text 'Please enter data' is visible at the bottom left of the dialog area.

Searching for Studies by Keyword

Scenario Element:

The CRS is searching for correlative studies, so she or he clicks on the “Search for words in correlative study Titles” radio button.

The screenshot shows the 'Select Studies' dialog box with the following elements:

- Tabbed interface: 'by IDB Monitor', 'by Agent', 'by Principal Investigator', 'by Institution', 'by Disease', 'by Keyword' (selected), 'by IND No.'
- Keyword field: 'Please type a keyword here.'
- 'Find Studies' button.
- 'Titles to Search:' section:
 - ☐ Search for words in IDB study Titles
 - ☒ Search for words in correlative study Titles (indicated by a red arrow)
- 'Studies to Search:' section:
 - ☐ In Review
 - ☒ Active
 - ☐ Closed
 - ☐ Withdrawn
 - ☒ LOI
 - ☒ Protocol
- Empty list box for search results.
- 'Clear Selections' and 'Select All' buttons.
- 'Please enter data' text at the bottom left.
- 'OK' and 'Cancel' buttons at the bottom.

Tool Use

Users may search for studies in which a specified keyword appears in the study title. The user may search either regular study titles or the titles of correlative studies.

Searching for Studies by Keyword

Scenario Element:

The CRS refines the search to include studies that are In Review, Active, or Closed.

Select Studies

by IDB Monitor | by Agent | by Principal Investigator | by Institution | by Disease | **by Keyword** | by IND No.

Keyword:

Find Studies

Titles to Search:

☐ Search for words in IDB study Titles ☒ Search for words in correlative study Titles

Studies to Search:

☒ In Review ☒ Active ☒ Closed ☐ Withdrawn ☒ LOI ☒ Protocol

Clear Selections

Select All

Please hit 'Find Studies' button to get study list

OK **Cancel**

Searching for Studies by Keyword

Scenario Element:

The CRS types the phrase “imag” in the Keyword box. Since this search is a text match, this phrase would match either “image” or “imaging.” The CRS then clicks on the “Find Studies” button.

Select Studies

by IDB Monitor | by Agent | by Principal Investigator | by Institution | by Disease | by Keyword | by IND No.

Keyword: Find Studies

Titles to Search:
☐ Search for words in IDB study Titles ☒ Search for words in correlative study Titles

Studies to Search:
☒ In Review ☒ Active ☒ Closed ☐ Withdrawn ☒ LOI ☒ Protocol

Clear Selections
Select All

Please hit 'Find Studies' button to get study list

OK Cancel

Tool Use

The keyword search is not case sensitive. However, it can only match a text string in a title. It does not allow complex search strategies such as those found on internet search engines.

Searching for Studies by Keyword

Scenario Element:

The IDB Drug Development Plan Tool returns six studies that meet the search criteria. The CRS clicks on the “Select All” button to select all six studies and then clicks the OK button to create a Gantt chart of them.

Select Studies

by IDB Monitor | by Agent | by Principal Investigator | by Institution | by Disease | **by Keyword** | by IND No.

Keyword: **Find Studies**

Titles to Search:

☐ Search for words in IDB study Titles ☒ Search for words in correlative study Titles

Studies to Search:

☒ In Review ☒ Active ☒ Closed ☐ Withdrawn ☒ LOI ☒ Protocol

DOC. NO.	TITLE	PHASE
T99-0001	LUTETIUM TEXAPHYRIN as a PHOTSENSITIZER for PHOTO...	I
S9900	A randomized PHASE III trial of SURGERY alone or SURGERY plu...	III
T99-0041	Phase I Trial of GADOLINIUM TEXAPHYRIN (PCI-0120) as a Radi...	I
T99-0059	A Phase I study of Oxaliplatin in children with solid tumors	I
T99-0072	A Phase I study of Oxaliplatin in children with solid tumors	I

Clear Selections **Select All**

To select more than one study, hold down the Ctrl key while clicking. **Records: 6**

OK **Cancel**

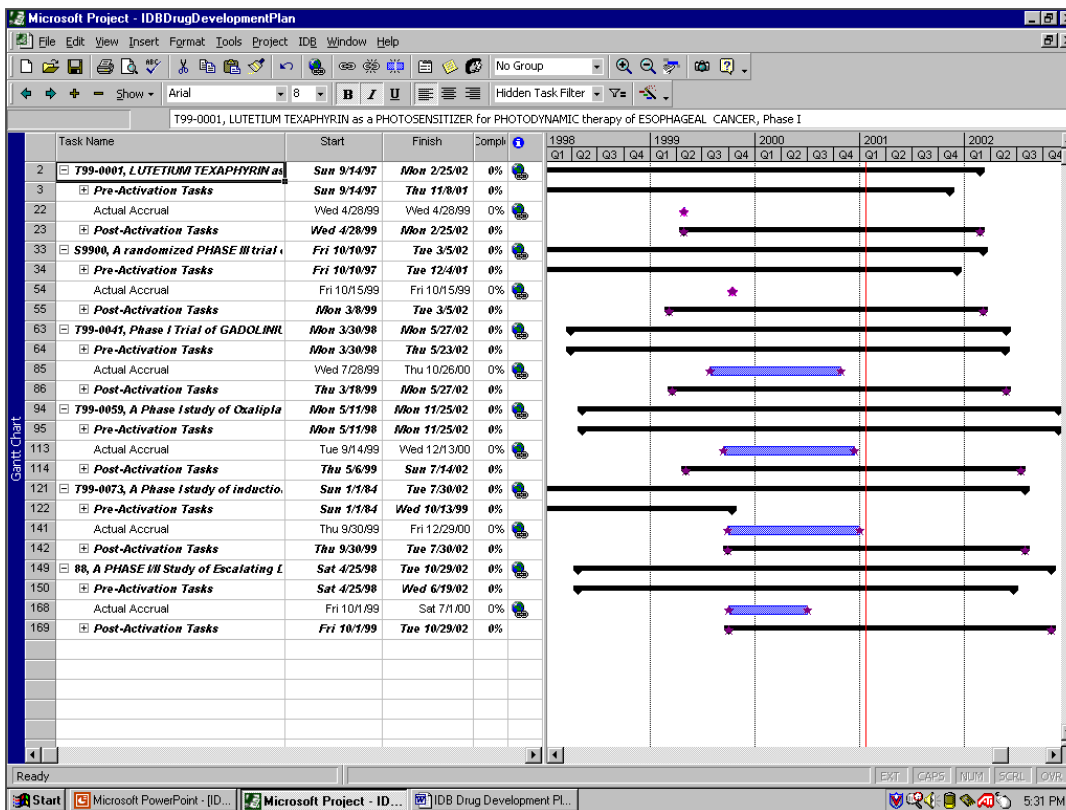
1

2

Searching for Studies by Keyword

Scenario Element:

The CRS reviews the studies that were charted and then saves them as a Favorite.



Tool Use

The user may chart multiple studies on the same Gantt chart. These studies may come from the same search or from several searches. The tool will continue adding new studies to the bottom of the Gantt chart until the user clears the chart.

Investigational Drug Branch Drug Development Plan Tool

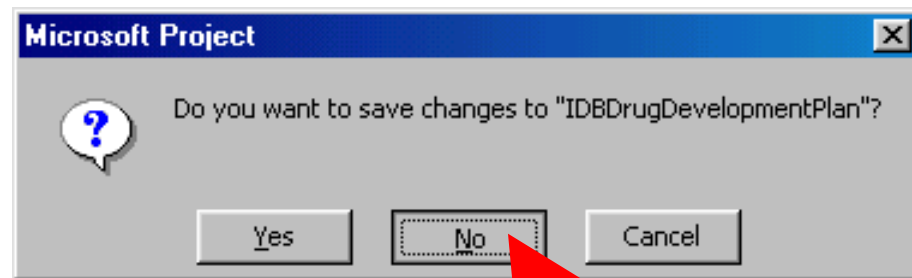
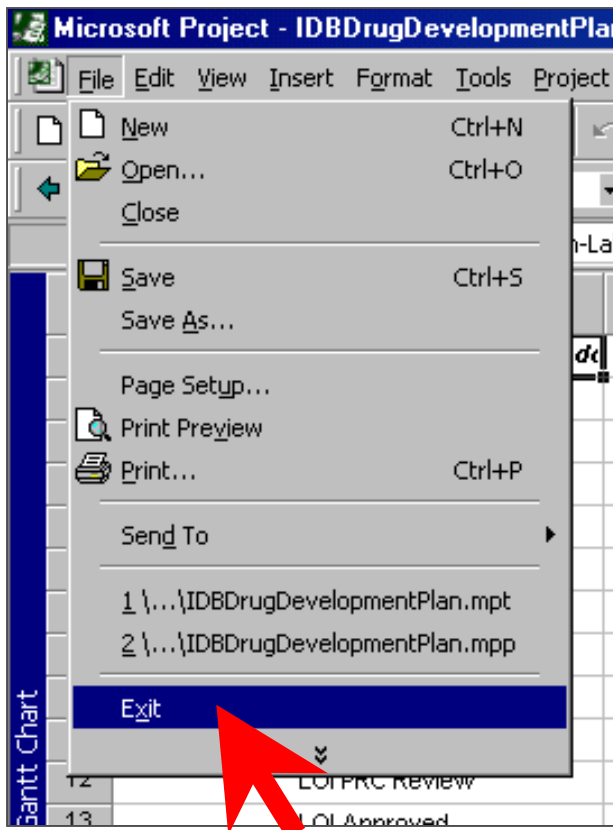


Exiting the IDB Drug Development Plan Tool

Exiting the Tool

Scenario Element:

The Clinical Research Specialist is done working with the IDB Drug Development Plan Tool and selects Exit from the File menu.



Tool Use

Microsoft Project will ask the user to save changes to "IDB Drug Development Plan". Any user-added notes or new tasks have already been saved and require no additional action from the user.

It is best to answer "No" when prompted to save the file. If the user wishes to save a specific Gantt chart, he or she may use the "Save As" feature described earlier.

Investigational Drug Branch Drug Development Plan Tool



Where to Go to Report Problems

Reporting Errors and Asking Questions

Please report possible application errors, and questions about the data. It will be most helpful if you can write down any error messages and make a note of exactly what you were doing in the tool when the error occurred.

Please report errors and problems to:

ctephelp@ctisinc.com

Please send questions about using the tool and ideas for improvement to:

ncisupport@scenpro.com